

REGION 6 EXECUTIVE SUMMARY
Compliance Assurance and Enforcement Division

TOPIC: Monarch Waste Technologies – Hospital/Medical/Infectious Waste Incinerator

DATE: January 30, 2019

CONTACT: Steve Thompson, 6EN-A

PURPOSE/ACTION NEEDED: Update – Performance Testing under Administrative Order on Consent

ACTION DATE: NA

BACKGROUND:

Monarch Waste Technologies, LLC (Monarch) has constructed a facility (the “Facility”) on Nambe Pueblo tribal land near Santa Fe, New Mexico, to destroy hospital, medical, and infectious wastes. In its October 2016 request to EPA Region 6 for an applicability determination, Monarch asserted that its Pyromed 550 System met the pyrolysis exclusion in the New Source Performance Standard (NSPS) for Hospital/Medical/Infectious Waste Incinerators (HMIWI) (Subpart Ec). If the system meets the exclusion, the Facility would not be regulated by any NSPS and would not be required to obtain a Title V operating permit.

In June 2017, Region 6 told Monarch that Region 6 was prepared to issue a formal applicability determination (final agency action) concluding that NSPS Subpart Ec is applicable to the Facility. Subsequently, Monarch withdrew its request and indicated to Region 6 that it planned to comply with NSPS Subpart Ec. On October 31, 2017, Region 6 conditionally approved Monarch’s petition for site-specific operating parameters for the air pollution control equipment to be used at the Facility, requiring submittal of a comprehensive Initial Performance Test plan and updated Waste Management Plan prior to testing. Monarch commenced commercial operations on November 20, 2017. However, Monarch immediately experienced an equipment failure, shut down the Facility for repairs, and did not begin operating again for several months.

On December 7, 2017, Region 6 Air Permits requested that Monarch provide a Title V operating permit application by June 1, 2018 (40 C.F.R. § 71.5). Upon Monarch’s later request, Region 6 Air Permits extended the application submittal due date to September 1, 2018. Region 6 Air Permits notified Monarch on November 19, 2018, that, because Monarch did not submit a complete operating permit application as required within twelve months of commencing operation, Monarch no longer had authority to operate.

Monarch has been unable to submit a complete Title V permit application because required elements of a complete permit application, i.e. completion of initial performance testing and reporting of the test results, have still not been done. After months of working with the Facility on an acceptable test plan, Monarch submitted a revised test plan on November 15, 2018, which EPA approved on November 19, 2018.

EPA and Monarch signed an Administrative Compliance Order on Consent (“AOC”) on December 4, 2018, that authorized Monarch to operate for the limited purpose of preparing for and conducting an initial performance test. After Monarch was unable to stabilize incinerator operations and conduct a



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representative test in mid-December, EPA and Monarch modified the AOC on December 21, 2018, to extend the deadline for completing the test to March 6, 2019.

CURRENT STATUS:

Monarch is also seeking an agency response on its updated applicability determination request regarding the Pyromed 550 System, which it sent to the EPA's Office of Enforcement and Compliance Assistance on December 9, 2018. The request states that Monarch believes the System should be exempt from the NSPS for Hospital/Medical/Infectious Waste Incinerators (Subpart Ec). Region 6 and OECA are reviewing the documents provided and preparing a response.

COMMUNITY CONCERNS:

There is significant interest from the Nambe Pueblo and NMED in ensuring that the Facility operates effectively and safely given Monarch's plans to destroy infectious materials. Other Pueblo governments near the facility have expressed concern about operations and inquired about the status of the Title V Permit.

RECOMMENDATIONS:

None at this time.



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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 6
BEFORE THE ADMINISTRATOR

In the Matter of

MWT NM, LLC
FACILITY ON THE NAMBE PUEBLO

Docket No. CAA 06 201 330

RESPONDENT.

ADMINISTRATIVE COMPLIANCE ORDER ON CONSENT

The following Administrative Compliance Order on Consent (“Consent Order”) is issued pursuant to the authority of Section 113(a)() of the Clean Air Act, 42 U.S.C. § 7413(a)() (hereinafter referred to as “CAA” or “the Act”). Section 113(a)() of the Act authorizes the Administrator of the United States Environmental Protection Agency (“EPA”) to issue an order requiring compliance to any person whom the Administrator finds to be in violation of the Act. The authority to issue this Consent Order has been delegated to the Regional Administrator of EPA Region 6, and re delegated to the Director of the Compliance Assurance and Enforcement Division, EPA Region 6.

STATUTORY AND REGULATORY BACKGROUND

1. The Act is designed to protect and enhance the quality of the nation’s air so as to promote public health and welfare and the productive capacity of its population. CAA § 101(b)(1), 42 U.S.C. § 7401(b)(1).

New Source Performance Standards for Solid Waste Incineration Units

2. Section 129(a)(1)(A) of the CAA, 42 U.S.C. § 7429, requires that the Administrator of the EPA establish performance standards pursuant to Section 111, 42 U.S.C. § 7411, for categories of solid waste incineration units. Congress further directed that these performance, or emission

standards shall reflect the maximum degree of reduction in emissions of air pollutants listed under Section 129(a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category

3. Section 129(a)(4) requires that performance standards promulgated under Sections 111 and 129 applicable to solid waste incineration units shall specify numerical emission limitations for particulate matter (total and fine), opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans. Further, the Administrator may promulgate numerical emissions limitations or provide for the monitoring of post combustion concentrations of surrogate substances, parameters or periods of residence time in excess of stated temperatures with respect to pollutants other than those listed above.

4. "solid waste incineration unit" was and is defined as a distinct operating unit of any facility which combusts any solid waste material from commercial or industrial establishments or the general public. 42 U.S.C. § 7429(g)(1).

5. "New solid waste incineration unit" was and is defined as a solid waste incineration unit the construction of which is commenced after the Administrator proposes requirements under Section 129 establishing emissions standards or other requirements which would be applicable to such unit. 42 U.S.C. § 7429(g)(3).

6. After the effective date of any performance standard, emission limitation or other requirement promulgated pursuant to Sections 129 and 111 of the CAA, it shall be unlawful for any owner or operator of any solid waste incineration unit to which such standard, limitation or

requirement applies to operate such unit in violation of such limitation, standard or requirement.
42 U.S.C. § 7429(f)(3).

Standards of Performance for New Stationary Sources: Hospital/Medical/Infectious Waste Incinerators

7. Pursuant to Sections 129 and 111 of the CAA, 42 U.S.C. §§ 7429 and 7411, EPA promulgated the New Source Performance Standards (NSPS) for Hospital/Medical/Infectious Waste Incinerators (HMIWI) 62 Fed. Reg. 48348 (Sept. 15, 1997), amended at 65 Fed. Reg. 61753 (Oct. 17, 2000); 74 Fed. Reg. 51402 (Oct. 6, 2009); 78 Fed. Reg. 28051 (May 13, 2013); and 79 Fed. Reg. 11249 (Feb. 27, 2014). These emission standards are codified at 40 C.F.R. Part 60, Subpart Ec, 40 C.F.R. §§ 60.50c–60.58c (“Subpart Ec”)

8. Subpart Ec provides that the “affected facility” to which Subpart Ec applies includes each individual HMIWI for which construction is commenced after December 1, 2008. 40 C.F.R. § 60.50c(a)(3).

9. “Hospital/medical/infectious waste incinerator” or “HMIWI” or “HMIWI unit” means any device that combusts any amount of hospital and/or medical/infectious waste. 40 C.F.R. § 60.51c.

10. “Hospital waste” means discards generated at a hospital, but does not include human corpses, remains, and anatomical parts that are intended for interment or cremation. *Id.*

11. “Medical/infectious waste” means any waste generated in the diagnosis, treatment, or immunization of human beings or animals. *Id.*

12. “Chemotherapeutic waste” means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells. *Id.*

13. Low level radioactive waste means waste material that contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable Federal or State standards for unrestricted release. Low level radioactive waste is not high level radioactive waste, spent nuclear fuel, or byproduct material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)). *Id.*

14. Commercial HMIWI” means a HMIWI which offers incineration services for hospital/medical/infectious waste generated offsite by firms unrelated to the firm that owns the HMIWI. *d.*

15. Continuous HMIWI” means a HMIWI that is designed to allow waste charging and ash removal during combustion. *Id.*

16. Large HMIWI means continuous or intermittent HMIWI whose maximum charge rate is more than 500 pounds per hour. *Id.*

17. “Startup” means the period of time between the activation of the system and the first charge to the unit. *Id.*

18. “Shutdown” means the period of time after all waste has been combusted in the primary chamber. For continuous HMIWI, shutdown shall commence no less than 2 hours after the last charge to the incinerator. *Id.*

19. “Operation” means the period during which waste is combusted in the incinerator excluding periods of startup or shutdown. *Id.*

20. 40 C.F.R. § 60.56c(b) provides that the owner or operator of an affected facility as defined in Section 60.50c(a)(3) must conduct an initial performance test as required under Section 60.8 to determine compliance with the emission limits using the procedures and test methods listed

in Section 60.56c(b)(1) (14) (specifying requirements for test runs and various EPA Reference Methods).

21. 40 C.F.R. § 60.56c(j) provides that the owner or operator of an affected facility using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, a dry scrubber followed by a fabric filter and a wet scrubber, or a selective noncatalytic reduction technology to comply with the emissions limits under Section 60.52c shall petition EPA for other site specific operating parameters to be established during the initial performance test and continuously monitored thereafter.

22. 40 C.F.R. § 60.8(a) states: “[W]ithin 60 days after achieving the maximum production rate at which the affected facility will be operated, but not later than 180 days after initial startup of such facility, or at such other times specified by this part, and at such other times as may be required by the Administrator under section 114 of the Act, the owner or operator of such facility shall conduct performance test(s) and furnish the Administrator a written report of the results of such performance test(s).

23. EPA is authorized by Section 113 of the Act, 42 U.S.C. § 7413, to take action to ensure that air pollution sources comply with all federally applicable air pollution control requirements. EPA is also authorized by Section 114 of the Act, 42 U.S.C. § 7414, to require any person who owns or operates an affected source to sample emissions in accordance with procedures or methods, at locations and intervals, and during periods as the EPA prescribes.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

24. MWT NM, LLC (“MWT” or “Respondent”) is a limited liability company doing business on the Nambe Pueblo, near Santa Fe, New Mexico. MWT is a “person” within the

meaning of Section 113(a) of the Act, 42 U.S.C. § 7413(a), and as defined in Section 302(e) of the Act, 42 U.S.C. § 7602(e).

25. At all times relevant to this Consent Order, MWT has owned and/or operated HMIWI on the Nambe Pueblo, at 45A Tova Muusa Poe Santa Fe, New Mexico 87506 [Lat/Long Coordinates 35 50 57.47N and 105 58 55.79W] (the Facility”). The terms of this AOC apply only to this Facility.

26. MWT is the owner and/or operator of the Facility within the meaning of Section 111(a)(5) of the Act, 42 U.S.C. § 7411(a)(5), and 40 C.F.R. § 60.2.

27. At all times relevant to this Consent Order, MWT owned and/or operated units that incinerate hospital/medical/infectious waste, including chemotherapeutic and low level radioactive waste, at the Facility.

28. The Facility is a “stationary source” as that term is defined in Section 111(a)(3) of the Act, 42 U.S.C. § 7411(a)(3), and 40 C.F.R. § 60.2.

29. Pursuant to 40 C.F.R. § 60.50c, the Facility is an “affected facility” because MWT commenced construction of the Facility after December 1, 2008. *See* 74 Fed. Reg. 51374 (Oct. 6, 2009).

30. The Facility operates a Commercial HMIWI that is further classified as a Large Continuous HMIWI under 40 C.F.R. § 60.51c.

31. During September and October of 2017, EPA provided technical assistance to MWT regarding a petition necessary to propose site specific operating parameters to be established in accordance with 40 C.F.R. § 60.56c(j); MWT submitted the petition on October 19, 2017

32. On October 31, 2017, EPA conditionally approved MWT’s petition. One condition of approval required MWT to submit a comprehensive plan for conducting the initial performance

test (“IPT”) that would address technical deficiencies identified in the draft plan submitted with the petition and to incorporate testing for establishing the site specific operating parameters identified by EPA’s approval. Another condition of approval included updating and submitting a waste management plan (WMP) that was consistent with all the different types of wastes being processed at the facility.

33. On November 20, 2017, MWT performed the initial startup of the Facility by activating the system and charging waste

34. MWT was required to conduct a performance test and furnish EPA a written report of the results of that performance test no later than 180 days after initial startup of the Facility, or May 18, 2018.

35. On March 9, 2018, EPA communicated to MWT that in order to obtain IPT results and submit a report required by the 180 day deadline of May 18, 2018, the initial Performance Test plan “IPT Plan” or “Plan”) must be submitted for review and approval as soon as possible in order to proceed with scheduling the test.

36. On May 10, 2018, MWT submitted a draft IPT Plan to EPA by e mail.

37. On May 17, 2018, EPA communicate to MWT that the draft IPT Plan lacked required information and that an extension for conducting the IPT could not be granted under NSPS. EPA offered to provide technical assistance and to work with MWT to complete an approvable IPT Plan in an expedited manner.

38. From June through November 2018, MWT worked with EPA to complete the necessary planning for the IPT, including consideration of all changes made to operations since submittal of the first test plan and details not initially provided in prior draft plans (e.g., change from propane

fuel to use of diesel during winter months, changes to types of waste being processed, development of test condition for representative performance testing at potentially worst case emissions, etc.)

39. As of the effective date of this Consent Order, MWT has not conducted an IPT or furnished EPA a written report of the results of such performance test.

40. EPA finds that MWT has violated 40 C.F.R. §§ 60.56c(b) and 60.8(a) by failing to conduct an IPT and furnish EPA the written results of that performance test no later than 180 days after initial startup of the HMIWI

41. On November 1 , 2018, MWT submitted to EPA a complete IPT Plan that included applicable procedures and test methods required by 40 C.F.R. § 60.56c(b) and also descriptions of operational test condition and objectives necessary for demonstrating compliance with all emission limitations in accordance with 40 C.F.R. 60.8(c); the IPT Plan also provided test objectives and information necessary for establishing site specific operating parameter limits (“OPLs”) required by EPA’s conditional approval of MWT’s Petition under 40 C.F.R. § 60.56c(j); the IPT Plan also provided objectives and test protocols for certification of continuous emissions monitoring systems (“CEMS”) On November 16, 2018, MWT also submitted an updated WMP that was consistent with the corresponding IPT Plan submittal content.

42. EPA approved MWT’s IPT Plan on November 19, 2018.

43. On November 27 and 29, 2018, MWT conferred with EPA via teleconference to discuss the violation alleged herein.

44. The parties further agree that in order to avoid protracted litigation, and in the best interest of all the parties and the environment, this Consent Order will be entered into on Consent and by mutual agreement of the parties.

45. Only for the purposes of issuance of this Consent Order and any subsequent proceeding by EPA to enforce this Consent Order, MWT admits the jurisdictional allegations contained herein; however, MWT neither admits nor denies any of the findings of fact and conclusions of law contained in this Consent Order.

46. MWT also consents to and agrees not to contest EPA's jurisdiction to either issue this Consent Order or enforce its terms. Further, MWT will not contest EPA's jurisdiction to compel compliance with this Consent Order in any subsequent enforcement proceedings, whether administrative or judicial, require MWT's full compliance with the terms of this Consent Order or impose sanctions for violations of this Consent Order. Without admitting or denying any of the findings of fact and conclusions of law contained in this Consent Order, MWT consents to the terms of this Consent Order.

ORDER ON CONSENT

47. Section 113(a)() of the Act, 42 U.S.C. § 7413(a)(), provides in pertinent part that the Administrator may issue an order requiring compliance with any requirement of the NSPS. Pursuant to this authority, EPA has decided to issue this Consent Order after investigating all relevant facts, taking into account MWT's compliance history, efforts made by MWT's effort to comply with applicable regulations, and based upon the foregoing Findings of Fact and Conclusions of Law herein.

48. MWT has consented to, and is hereby ordered to satisfy, the following requirements regarding its Facility on the Nambe Pueblo

- a. Prior to commencing the IPT, MWT may begin Startup and Operation of the HMIWI for pre IPT Operation, in accordance with the protocols contained within MWT's WMP. The pre IPT Operation is limited to a total duration up

- to 16 hours, with the purpose of ensuring functionality of all equipment, including operation of the waste charging system, the CEMS, the overall system programmable logic controls, and all related monitoring sensors and auxiliary equipment, necessary for conducting a safe and representative IPT program
- b. All hours of pre IPT Operation will be logged in a field notebook with type of activities noted for discrete periods of Operation, separate of Startup and shutdown events MWT will maintain a copy of the log entries for 180 days and make them available to EPA upon request.
- c. By December 1 , 2018, MWT shall initiate mobilization of the equipment necessary to begin the IPT, in compliance with 40 C.F.R. § 60.56c and in accordance with MWT's IPT Plan submitted to EPA on November 1 , 2018 approved by EPA on November 19, 2018. Charging wastes for purposes of conducting the IPT is limited to the amount of time needed to complete all testing activities as outlined within the EPA approved IPT Plan, including certification of all CEMS that were functional prior to the start of the IPT. MWT will complete the IPT within 336 hours after mobilization of all equipment necessary to begin the IPT, including any hot standby mode of the HMIWI anticipated during times when waste charging is not necessary due to suspension(s) of testing activities (e.g., 48 hours for the planned weekend break in testing schedule or unplanned but necessary interruption(s) of testing activities

- d. Upon completion of the hours allowed to complete the IPT in item ., above, and no later than December 24, 2018, MWT shall stop all waste charging and proceed to safely perform a Shutdown of the HMIWI
- e. No later than 60 days after completion of the IPT, MWT shall furnish to EPA a written report of the results of the IPT and CEMS certifications (i.e. the IPT Report completed in accordance with MWT's IPT Plan, submitted to EPA on November 16, 2018, approved by EPA on November 19, 2018

49. This Consent Order only authorizes Startup Operations, and Shutdown as specified in Paragraph 48.

50. Any information or correspondence submitted by MWT to EPA under this Consent Order shall be addressed to the following

Cynthia Kaleri
Enforcement Officer (6EN AA
Air Enforcement Section
Compliance Assurance and Enforcement Division
U.S. EPA, Region 6
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202 2733
Email: kaleri.cynthia@epa.gov

51. To the extent this Consent Order requires MWT to submit any information to EPA, MWT may assert a business confidentiality claim covering part or all of that information, but only to the extent and only in the manner described in 40 C.F.R. § 2.203. EPA will disclose information submitted under a confidentiality claim only as provided in 40 C.F.R Part 2, Subpart B. See 41 Fed. Reg. 36,902 (Sept. 1, 1976). If MWT does not assert a confidentiality claim, EPA may make the submitted information available to the public without further notice to MWT. Emission data provided under Section 114 of the Act, 42 U.S.C. § 7414, is not entitled to

confidential treatment under 40 C.F.R Part 2, Subpart B. “Emission data” is defined in 40 C.F.R. § 2.301.

GENERAL PROVISIONS

52. Pursuant to Section 113(a)(4) of the Act, 42 U.S.C. § 7413(a)(4), this Consent Order shall be effective when fully executed, as set forth below in Paragraph 68 shall terminate upon completion of the actions set forth in Paragraph 48 (a) (e). MWT is ordered to comply with the actions in Paragraph 48(a) (e) within the schedules specified in Paragraph 48(a) (e), which are less than one year. The ordering provisions in this Consent Order shall be nonrenewable.

53. The provisions of this Consent Order shall apply to and be binding upon MWT, its officers, directors, agents, and employees solely in their capacity of acting on behalf of MWT

54. The provisions of this Consent Order shall be transferable to any other party, upon sale or other disposition of the Facility. Upon such action, the provisions of this Consent Order shall then apply to and be binding upon any new owner/operator, its officers, directors, agents, employees, and any successors in interest.

55. By signing this Consent Order, the undersigned representative of MWT certifies that he or she is fully authorized by MWT to execute and enter into the terms and conditions of this Consent Order and has the legal capacity to bind MWT to the terms and conditions of this Consent Order.

56. Nothing in this Consent Order shall be construed to affect EPA’s authority under Section 114 of the Act, 42 U.S.C. § 7414.

57. Nothing in this Consent Order shall be construed to prevent or limit EPA’s civil and criminal authorities, or that of other Federal, State, or local agencies or departments to obtain compliance, penalties, or injunctive relief under any applicable Federal, State, or local laws or

regulations, including the power of the EPA to undertake any action against MWT or any person in response to conditions that may present an imminent and substantial endangerment to the public health, welfare, or the environment.

58. Nothing contained in this Consent Order shall affect the responsibility of MWT to comply with all other applicable Federal, State, or local laws or regulations, including Section 303 of the Act, 42 U.S.C. § 7603.

59. EPA does not waive any rights or remedies available to EPA for any violations by MWT of Federal laws, regulations, statutes, or permitting programs.

60. Any and all information required to be maintained or submitted pursuant to this Consent Order is not subject to the Paperwork Reduction Act of 1995, 44 U.S.C. §§ 3501 et seq., because it seeks to collect information from specific entities to assure compliance with this administrative action.

61. By signing this Consent Order, MWT acknowledges that this Consent Order will be available to the public and agrees that this Consent Order does not contain any confidential business information.

62. By signing this Consent Order, MWT certifies that the information it has supplied concerning this matter was at the time of submission, and is, to the best of its knowledge and belief, truthful, accurate, and complete for each submission, response, and statement, unless such submission, response or statement was subsequently supplemented or otherwise revised. MWT acknowledges that there are significant penalties for submitting false or misleading information, including the possibility of fines and imprisonment for knowing submission of such information, under 18 U.S.C. § 1001.

63. EPA reserves all of its statutory and regulatory powers, authorities, rights, and remedies, both legal and equitable, which may pertain to MWT's failure to comply with any of the requirements of this Consent Order. This Consent Order shall not be construed as a covenant not to sue, release, waiver, or limitation of any rights, remedies, powers, and/or authorities, civil or criminal, which EPA has under any statutory, regulatory, or common law authority of the United States.

64. This Consent Order does not resolve any civil or criminal claims of the United States for the violations alleged in this Consent Order; nor does it limit the rights of the United States to obtain penalties or injunctive relief under the Act or other applicable federal law or regulations.

65. MWT has entered into this Consent Order in good faith without admitting or denying any of the findings of fact or conclusions of law contained in this Consent Order, and without trial or adjudication of any issue of fact or law.

66. MWT waives any and all remedies, claims for relief and otherwise available rights to judicial or administrative review that MWT may have with respect to any issue of fact or law set forth in this Consent Order, including any right of judicial review under Section 307(b)(1) of the Act, 42 U.S.C. § 7607(b)(1), provided MWT reserves any of its rights and defenses that may be asserted in any action brought to enforce the terms of this Consent Order

67. The parties shall bear their own costs and fees in this action, including attorneys' fees.

FAILURE TO COMPLY

68. Failure to comply with this Consent Order may result in an enforcement action for appropriate injunctive relief as well as civil penalties pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b) or, in appropriate cases, criminal penalties.

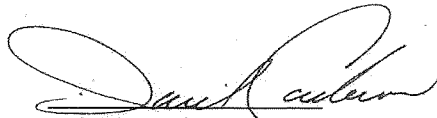
Re: Monarch Waste Technologies, LLC
Docket No. CAA-06-2019-3308

EFFECTIVE DATE

69. This Consent Order shall become effective upon the later of the two signatures below.

12-3-18

Date



David Cardenas, CEO
Monarch Waste Technologies, LLC
8501 Washington St NE
Albuquerque, NM 87113

12-4-18

Date



Cheryl T. Seager
Director
Compliance Assurance and
Enforcement Division

Re: Monarch Waste Technologies, LLC
Docket No. CAA-06-2019-3308

CERTIFICATE OF SERVICE

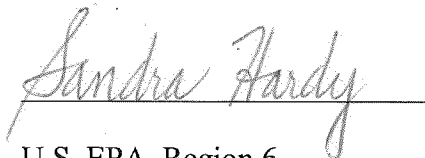
I hereby certify that on the 4th day of December, 2018, true and accurate copy of the foregoing Administrative Order on Consent was placed in the United States mail to the following by the method indicated below:

CERTIFIED MAIL - RETURN RECEIPT REQUESTED 70073620000015227918

David Cardenas, CEO
Monarch Waste Technologies, LLC
8501 Washington St NE
Albuquerque, NM 87113

CERTIFIED MAIL - RETURN RECEIPT REQUESTED 70073620000015227901

Eric L. Burton, Registered Agent
8801 Jefferson St. NE, Bldg C
Albuquerque, NM 87113

A handwritten signature in cursive script, reading "Sandra Hardy", is written over a horizontal line.

U.S. EPA, Region 6
Dallas, Texas

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 6
BEFORE THE ADMINISTRATOR

| | | |
|------------------------------|---|-----------------------------|
| In the Matter of |) | |
| |) | |
| MWT NM, LLC |) | Docket No. CAA-06-2019-3308 |
| FACILITY ON THE NAMBE PUEBLO |) | |
| |) | |
| RESPONDENT. |) | |
| |) | |

MODIFICATION OF ADMINISTRATIVE COMPLIANCE ORDER ON CONSENT

On December 4, 2018, MWT NM, LLC (“MWT”) and the United States Environmental Protection Agency (“EPA”) entered into an Administrative Compliance Order on Consent (“Consent Order”) in the above-entitled case. The Consent Order authorizes MWT to perform an Initial Performance Test (“IPT”) and to undertake pre-IPT activities necessary for conducting a safe and representative IPT program at its hospital/medical/infectious waste incinerator (“HMIWI” or “Facility”). The Consent Order provides limits on the number of hours MWT may operate its HMIWI for both pre-IPT operations and the IPT and requires MWT to complete the IPT no later than December 24, 2018.

Between December 5, 2018 and December 14, 2018, MWT performed some pre-IPT and IPT activities. However, MWT was not able to properly stabilize HMIWI operations in order to conduct a safe and representative IPT. On December 14, 2018, MWT demobilized and shut down the HMIWI.

On December 19, 2018, MWT requested that the Consent Order be modified to allow MWT to have until February 20, 2019, to complete pre-IPT activities, at which time MWT will thereafter re-start the IPT. As a result, the deadline to complete the IPT in Paragraph 48.d. of the

Consent Order is being changed from December 24, 2018, to March 6, 2019. See, i.e., new Paragraph 48.e., below.

This Modification is entered into by EPA and MWT and represents the mutual agreement of EPA and MWT to amend the Consent Order. All other provisions of the Consent Order remain unchanged and in full effect.

The Parties agree that Paragraph 48 of the Consent Order is modified as follows:

48. MWT has consented to, and is hereby ordered to satisfy, the following requirements regarding its Facility on the Nambe Pueblo:

- a. Prior to commencing the IPT, MWT may begin Startup and Operation of the HMIWI for pre-IPT Operation, in accordance with the protocols contained within MWT's WMP. The pre-IPT Operation is limited to a total duration up to 216 hours, with the purpose of ensuring functionality of all equipment, including operation of the waste charging system, the CEMS, the overall system programmable logic controls, and all related monitoring sensors and auxiliary equipment, necessary for conducting a safe and representative IPT program.
- b. All hours of pre-IPT Operation and the IPT will be logged in a field notebook with types of activities noted for discrete periods of Operation, separate of Startup and Shutdown events. MWT will maintain a copy of the log entries for 180 days and provide a copy of all log entries to EPA on a weekly basis during both the pre-IPT and IPT time periods defined in items a, c, and d of this paragraph, unless already provided, until such time as the IPT is completed.

- c. By December 10, 2018, MWT shall initiate mobilization of the equipment necessary to begin the IPT, in compliance with 40 C.F.R. § 60.56c and in accordance with MWT's IPT Plan, submitted to EPA on November 16, 2018, approved by EPA on November 19, 2018. Charging wastes for purposes of conducting the IPT is limited to the amount of time needed to complete all testing activities as outlined within the EPA approved IPT Plan, including certification of all CEMS that were functional prior to the start of the IPT. MWT will complete the IPT within 336 hours after mobilization of all equipment necessary to begin the IPT, including any hot standby mode of the HMIWI anticipated during times when waste charging is not necessary due to suspension(s) of testing activities (e.g., 48 hours for the planned weekend break in testing schedule) or unplanned but necessary interruption(s) of testing activities.
- d. Because demobilization and Shutdown occurred on December 14, 2018, prior to completing the IPT, the unused hours from the allotments specified in items a and c of this paragraph did not expire upon demobilization and Shutdown. MWT may apply the unused pre-IPT Operation hours to undertake the pre-IPT activities described in item a of this paragraph. Further, MWT may apply the unused mobilization and IPT hours to remobilize and conduct the IPT as described in item c of this paragraph and in accordance with MWT's IPT Plan.
- e. Upon completion of the unused hours allowed to conduct and complete the IPT, and no later than March 6, 2019, MWT shall stop all waste charging and proceed to safely perform a Shutdown of the HMIWI.

Re: Monarch Waste Technologies, LLC
Docket No. CAA-06-2019-3308

- f. No later than 60 days after completion of the IPT, MWT shall furnish to EPA a written report of the results of the IPT and CEMS certifications (i.e. the IPT Report completed in accordance with MWT's IPT Plan, submitted to EPA on November 16, 2018, approved by EPA on November 19, 2018).

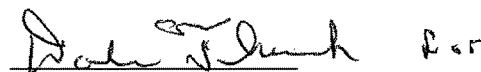
This Modification shall become effective upon the later of the two signatures below.

12-21-18
Date



David Cardenas, CEO
Monarch Waste Technologies, LLC
8501 Washington St NE
Albuquerque, NM 87113

12.21-18
Date



Cheryl T. Seager
Director
Compliance Assurance and
Enforcement Division

From: [David Cardenas](#)
To: [Braganza, Bonnie](#)
Cc: [Kevin Yearout](#)
Subject: Time extension request
Date: Wednesday, May 30, 2018 2:51:06 PM
Attachments: [image002.png](#)
[Extention request.pdf](#)

Bonnie, I hope your Memorial day weekend was safe and relaxing. As per the email from Jeff Robinson requesting we submit a letter requesting additional time to file a Title V permit application along with other dialogue I have had with Cinthia and Steve Thompson concerning our performance tests, attached is a letter requesting a time extension regarding our facility in Nambe New Mexico. Thank you in advance for working with us on providing us this additional time.

All the best,

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

13601 Preston Road W1050 | Dallas | TX 75240

Albuquerque Office 505.884.0995 Main

8501 Washington St. NE | Albuquerque | NM 87113



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January 8, 2018

VIA CERTIFIED MAIL AND E-MAIL (Strauss.alexis@EPA.gov)

Alexis Strauss
Acting Regional Administrator
United States Environmental Protection Agency
Region IX
75 Hawthorne Street, Mail Code ORA-1
San Francisco, CA 94105-3901

Re: Request for Reconsideration of Applicability Determination Issued
to Aemerge RedPak Services Southern California, LLC

Dear Acting Administrator Strauss:

Pursuant to 40 CFR § 60.5, Aemerge RedPak Services Southern California, LLC (Aemerge RedPak) respectfully requests that U.S. EPA Region IX (Region IX) reconsider the applicability determination that it issued to Aemerge RedPak on April 7, 2017 regarding whether 40 CFR Part 60, Subpart Ec, Standards of Performance for New Stationary Sources: Hospital/Medical/Infectious Waste Incinerators (HMIWI Rule) applies to Aemerge RedPak's carbonizer/gasifier system located at 9600 E Avenue, Hesperia, California (Determination). Specifically, Aemerge RedPak requests that Region IX consider the supplemental information below together with the information previously submitted and issue a new applicability determination that Aemerge RedPak's facility is not subject to the HMIWI Rule and that Aemerge RedPak's pyrolysis system, including the thermal oxidizer, is exempt from the HMIWI Rule, and that Aemerge RedPak's system is not a solid waste incineration unit under Section 129 of the Clean Air Act (CAA).

Pyrolysis System Description

A conceptual description of the Aemerge RedPak carbonizer/gasifier system was included in Aemerge RedPak's original February 22, 2016 request for an applicability determination. Since the original request was made, the carbonizer/gasifier system has been permitted by the Mojave Desert Air Quality Management District (Permit Nos. B012414, B012415, C012416 and C012421) and construction is now substantially complete.

In summary the constructed carbonizer/gasifier system consists of the following components: a custom manufactured sealed pyrolysis chamber (carbonizer/gasifier); a furnace using 32 natural gas-fired burners to provide indirect heat to the pyrolysis chamber; a thermal oxidizer without integrated heat recovery using a single natural gas-fired burner; a heat exchanger; and an emergency enclosed flare (these components are collectively referred to as the "pyrolysis system"). Add-on air pollution controls consist of a baghouse and dry sorbent injection system using hydrated lime. Hospital, medical and infectious waste (HMIW) is processed in sealed

containers through a grinder and fed into the pyrolysis chamber. The pyrolysis chamber is capable of processing up to 7,750 pounds of HMIW per hour. The pyrolysis chamber employs multiple airlocks to prevent air and oxygen from entering the chamber, the chamber is constantly monitored to assure that it is maintained under negative pressure throughout the system and that its nitrogen atmosphere is below 7-8% oxygen. The furnace supplies indirect external heat to the pyrolysis chamber to enable endothermic gasification of the HMIW. The pyrolysis process treats and destroys the HMIW by thermally converting the HMIW into syngas (carbon molecules in vapor form), carbon solids (char), and inert recyclable glass and high quality metals. The char, glass and metals are removed from the pyrolysis chamber while maintaining the nitrogen atmosphere and can be beneficially recycled into a variety of applications. The syngas and purge nitrogen is routed to a thermal oxidizer where it is currently combusted into CO₂ which is then sent to a tube boiler where steam generation is used to reduce the CO₂'s temperature so it safely can be sent to a baghouse (the design allows for a heat recovery steam powered electrical generator to be installed in the future).

The facility also includes a smaller pyrolysis unit using an indirect heater with one natural gas fired burner that can process up to a maximum of 100 pounds of pathological waste per hour. The syngas from this pyrolysis unit exhausts to a venture scrubber and then to an enclosed flare (Permit Nos. B012518, C012519 and C012520). A 276 bhp natural gas fired emergency power generator is also present at the facility (Permit No. E012422) (a request to change to diesel fuel will be made). The facility is permitted for a third pyrolysis system; however, it has not been installed.

Aemerge Redpak's Pyrolysis System is Exempt from the HMIWI Rule.

Pursuant to 40 CFR § 60.50c(f), any pyrolysis unit is not subject to any requirements of the HMIWI Rule (Pyrolysis Unit Exemption).

In the Determination, Region IX agreed that the endothermic destruction of HMIW in Aemerge RedPak's pyrolysis chamber meets the definition of "pyrolysis"; however, Region IX in its Determination stated that the Pyrolysis Unit Exemption is not applicable to Aemerge RedPak's pyrolysis system because the thermal oxidizer used to combust the syngas is exothermic. Region IX stated: "Therefore, because the Aemerge system is not 'endothermic' throughout its system, we do not believe that the Aemerge system meets the exemption for 'any pyrolysis unit' as 'pyrolysis' is defined in the HMIWI standards." *See* Determination at p. 3.

Region IX's determination that the Pyrolysis Unit Exemption is not applicable to Aemerge RedPak's pyrolysis system appears to be based solely upon Region IX's interpretation of the definition of "pyrolysis" found at 40 CFR § 60.50c: "the endothermic gasification of hospital waste and/or medical/infectious waste using external energy." However, this definition only defines the pyrolysis process itself for the purpose of differentiating the pyrolysis process from the incineration process, and it does not define the term "unit" as used in "pyrolysis unit" or limit the system components comprising a "pyrolysis unit" as used in the Pyrolysis Unit Exemption.

Because a definition of the term “pyrolysis unit” is not included in the HMIWI Rule, it is necessary to examine other provisions of the HMIWI Rule, documents published by U.S. EPA during the development of the HMIWI Rule, and prior U.S. EPA determinations to establish U.S. EPA’s intended scope of the Pyrolysis Unit Exemption.

Beginning with the February 27, 1995 initial notice of the proposed HMIWI Rule, it was already evident that U.S. EPA viewed pyrolysis systems as a potential candidate for regulation as a source category separate from incineration. *See*, 60 Federal Register 10654, 10658 (February 27, 1995). After further investigation of pyrolysis systems, U.S. EPA became more convinced pyrolysis systems should not be regulated under the HMIWI Rule. In the June 20, 1996 notice of the re-proposal of the HMIWI Rule, U.S. EPA announced that “it is inclined to adopt separate regulations for pyrolysis treatment technologies.” U.S. EPA acknowledged that pyrolysis systems “appear to be very different than incinerators.” Because of their unique and then emerging nature, U.S. EPA said it was not possible to determine MACT for pyrolysis systems at that time. 61 Federal Register 31736, 31753 (June 20, 1996).

As part of the 1996 re-proposal of the HMIWI Rule, U.S. EPA sought comments upon draft Standards of Performance for Medical Waste Pyrolysis Units (Draft MWP Rule). *See* Legacy Air Docket A-91-61, IV-B-56. The definitions included in the Draft MWP Rule clearly evidence U.S. EPA’s intent to define a pyrolysis unit as a process that includes both a primary pyrolysis chamber and a secondary oxidation chamber. U.S. EPA defined “medical waste pyrolysis (MWP)” as “the endothermic gasification of medical waste using external energy.” “Primary chamber” is defined in the Draft MWP Rule as the heated portion of the MWP in which the waste is introduced. “Secondary chamber” is defined in the Draft MWP Rule as “*the portion of the MWP where final oxidation of pyrolysis gases occurs*” (emphasis added). The Draft MWP Rule’s definition of “identical medical waste pyrolysis (mwp) unit” also specifically refers to the secondary oxidation chamber as a part of the MWP unit, again clearly demonstrating that U.S. EPA intended the term “pyrolysis unit” to include a thermal oxidizer.

In the September 15, 1997 notice of the final HMIWI Rule, U.S. EPA announced its decision to exempt pyrolysis units completely from the HMIWI Rule and to defer development of a separate regulation covering pyrolysis systems. U.S. EPA concluded that “sufficient information is not available to develop a separate and uniform regulation for pyrolysis technology that would contain requirements that are technically feasible for all pyrolysis units.” 62 Federal Register 48348, 48359 (September 15, 1997).

Importantly, U.S. EPA also declined to modify the HMIWI Rule to include pyrolysis units, stating:

“However, nearly all aspects of the HMIWI regulations would have to be altered to accommodate pyrolysis units including the format of the emission limits, the operator training requirements, siting requirements, and the reporting

and recordkeeping requirements. Further, the HMIWI subcategories and MACT floors would not be appropriate for pyrolysis units.

...

As discussed above, pyrolysis and conventional incineration are not the same. Because regulations developed for HMIWI are not appropriate for pyrolysis technologies, pyrolysis treatment technologies have specifically been excluded from coverage under the final HMIWI standards and guidelines.” *Id.*

Given that at the very time that the Pyrolysis Unit Exemption was promulgated U.S. EPA understood that pyrolysis systems include both a pyrolysis component and an oxidation component and clearly manifested its understanding and intent in the Draft MWP Rule by defining pyrolysis units as consisting of a primary pyrolysis chamber and secondary oxidation chamber, it is clear that U.S. EPA exempted the entire pyrolysis system, including the oxidation component, from the HMIWI Rule. There is no suggestion in the HMIWI Rule or the rulemaking documents that the exemption was conditioned on the absence of a secondary oxidation chamber or thermal oxidizer. Such a partial or conditional exemption would have required substantial modification of the HMIWI Rule in order to appropriately address a pyrolysis chamber/thermal oxidizer system – something U.S. EPA explicitly said it would not undertake.

U.S. EPA reiterated this point in its response to public comments: “Due to variations in the operating characteristics of pyrolysis technologies and the differences between MWI and pyrolysis technologies, it is unclear how the MWI regulations could be modified to feasibly cover pyrolysis technologies as well as MWI.” *See* Summary of Public Comments and Responses at p. 3-102 (EPA-453/R-97-006b July 1997). U.S. EPA could not have been more clear: “Because of the inherent differences between MWI and pyrolysis treatment technologies, the EPA agrees that pyrolysis units do not belong within the source category regulated under the MWI standards and guidelines.” *Id.*

In its Determination Region IX acknowledged and agreed that for the purpose of the Pyrolysis Unit Exemption, a pyrolysis unit includes the thermal oxidizer, noting that Aemerge RedPak’s pyrolysis chamber and thermal oxidizer “operate as a multi-component thermal system” and that the oxidizer is integral to the process. *See* Determination, at p. 3. However, Region IX’s reading of the Pyrolysis Unit Exemption to be available only where the pyrolysis gases are not combusted by a thermal oxidizer is contrary to the HMIWI Rule and supporting rulemaking documents. Nothing in the HMIWI Rule or any of the rulemaking documents limits the Pyrolysis Unit Exemption to only pyrolysis technologies that do not involve combustion of pyrolysis gases. Throughout the rulemaking record, references are made to pyrolysis chambers with oxidation chambers, pyrolysis *systems* and pyrolysis *technologies*. If U.S. EPA intended to narrowly limit the Pyrolysis Unit Exemption to exclude pyrolysis systems that include an oxidation component, U.S. EPA could easily have included limiting language in the exemption. Instead it chose to phrase the exemption in simple and broad terms in order to exempt the entire

pyrolysis system, including the oxidation component, and avoid the difficulties of modifying the HMIWI Rule to include pyrolysis systems.

It is believed the vast majority of all pyrolysis systems now in use include an oxidation component. Region IX's interpretation that any exothermic combustion of the pyrolysis gases in a thermal oxidizer renders the exemption unavailable effectively eviscerates the Pyrolysis Unit Exemption in its entirety. In addition to being unsupported by the HMIWI Rule and the rulemaking record, Region IX's interpretation is inconsistent with U.S. EPA's prior applicability determinations.

Region IX's Interpretation Is Inconsistent with Prior U.S. EPA Determinations.

Shortly after the promulgation of the HMIWI Rule in 1997 (62 Federal Register 48348 (September 15, 1997)), U.S. EPA issued two separate applicability determinations, each of which found that the Pyrolysis Unit Exemption is available where pyrolysis gases are combusted in a thermal oxidizer.

On June 23, 1999, U.S. EPA's Office of Enforcement and Compliance Assurance (OECA) issued an applicability determination to Environmental Techniques (ET) finding that ET's proposed pyrolysis system consisting of a pyrolysis chamber and an oxidation chamber used to combust the pyrolysis gases met the definition of pyrolysis (ET Determination). U.S. EPA found the entire pyrolysis system, including the thermal oxidizer, to be exempt as a pyrolysis unit as long as it was designed as described. U.S. EPA expressly found that no waste was introduced to the oxidation chamber, stating:

"The key features of your device which lead us to conclude that it could meet the definition of pyrolysis, if it was designed and operated in the manner you outlined, include the fact that the *waste is placed in a sealed chamber separate from the oxidation chamber*, heat is continually transferred to the pyrolysis chamber from outside (*i.e.*, from the oxidation chamber), and the total amount of oxygen in the pyrolysis chamber is relatively small compared to a typical incineration."

See ET Determination, at p. 2 (emphasis added). This statement clearly evidences that U.S. EPA did not consider the pyrolysis gases to be a waste.

It is particularly notable that the ET Determination was coordinated with Region IX. OECA also coordinated the SMS Determination with Rick Copeland, U.S. EPA Office of Air Quality, Planning and Standards (OAQPS). Mr. Copeland led the development of the HMIWI Rule and drafting of the Draft MWP Rule on behalf of U.S. EPA. For these reasons Mr. Copeland was in the best position to provide U.S. EPA's interpretation of the intended scope of the Pyrolysis Unit Exemption to include pyrolysis systems using a thermal oxidizer to combust pyrolysis gases.

In the Determination issued to Aemerge RedPak, Region IX did not mention the ET Determination or explain why it is now deviating from its own and OECA's 1999 conclusion that the Pyrolysis Unit Exemption applies where a thermal oxidizer is used to combust pyrolysis gases. Nor did it explain why it was no longer following the ET Determination's recognition that pyrolysis gases are not waste. Region IX's failure to distinguish a prior Determination, particularly a determination in which it was an active participant, without even mentioning the prior determination renders the Determination issued to Aemerge RedPak improper, arbitrary and capricious, and contrary to established interpretations. To avoid this outcome, Region IX must make a determination that is consistent with its own prior determination or clearly articulate a reasonable rationale for deviating from the ET Determination that the Pyrolysis Unit Exemption includes a thermal oxidizer used to combust pyrolysis gases and pyrolysis gases are not a waste. *See*, U.S. EPA Memorandum, "How to Review and Issue Clean Air Act Applicability Determinations and Alternative Monitoring" (February 1999), at p. 52 (If a previous determination seems to contradict our current determination, explain how the current case is different").

The second applicability determination was issued by U.S. EPA Region 5 (Region 5) to the Indiana Department of Environmental Management (IDEM) on February 2, 2000, finding that a pyrolysis system to be operated by Statewide Medical Services (SMS), consisting of a pyrolysis chamber and an oxidation chamber, met the definition of pyrolysis in the HMIWI Rule as long as the system monitored compliance with certain operating parameters (SMS Determination). Again, the existence of a thermal oxidizer did not disqualify SMS's pyrolysis system from the Pyrolysis Unit Exemption. Rick Copeland of OAQPS, U.S. EPA's foremost expert on the HMIWI Rule and the Draft MWP Rule, also was involved with the SMS Determination.

IDEM subsequently issued Registration No. 097-11795-00339 to SMS on February 3, 2000, specifically finding that SMS' pyrolysis system was a pyrolysis unit and therefore exempt from the HMIWI Rule. *See* Registration, at pp. 4 and 6. U.S. EPA did not object to the Registration. Subsequently, Region 5 sent a letter to IDEM on October 22, 2001 reaffirming that the SMS pyrolysis system was exempt from the HMIWI Rule.

Region IX made no attempt to distinguish the SMS Determination from Aemerge RedPak's pyrolysis system, instead only stating it was not revisiting the SMS Determination. *See* Determination, at p. 7. By providing no rationale for deviating from Region 5 and the OAQPS' conclusion that the Pyrolysis Unit Exemption encompasses the entire pyrolysis system, including the thermal oxidizer, the Determination is improper, arbitrary and capricious and contrary to established U.S. EPA guidance. Curiously, Region IX noted that the SMS Determination predated a court ruling in *NRDC v. EPA*, 489 F.3d 1250 (D.C. Cir. 2007) without offering an explanation why the decision is relevant to the Pyrolysis Unit Exemption and merely repeating its opinion that the Aemerge RedPak pyrolysis system combusts HMIWI and therefore does not meet the Pyrolysis Unit Exemption.

Region IX's reference to the *NRDC v. EPA* decision is misplaced and does not justify disregarding the SMS Determination because *NRDC v. EPA* did not address the scope of the Pyrolysis Unit Exemption. In *NRDC v. EPA*, the court vacated the CISWI Definitions Rule (70 Federal Register 55568 (September 22, 2005)), finding that U.S. EPA's definition of "commercial and industrial waste" that excluded certain combustion units designed to permit thermal energy recovery or being used for thermal energy recovery as inconsistent with the wording of 42 USC § 7429(g)(1) (Section 129 of the Clean Air Act (CAA)). 489 F.3d 1250, at 1258. The CISWI Definitions Rule was completely different and separate from the HMIWI Rule's Pyrolysis Unit Exemption. The CISWI Definitions Rule attempted to permanently exclude from regulation certain combustion units based on a unit's function. The Pyrolysis Unit Exemption, in contrast, was included in the HMIWI Rule to effect a temporary deferral of the regulation of pyrolysis systems until a separate rulemaking solely for pyrolysis systems could be completed due to, as U.S. EPA expressly acknowledged, the inappropriateness of applying the HMIWI Rule to pyrolysis technologies. *See* 62 Federal Register at p. 48359.

The HMIWI Rule was not before the court in *NRDC v. EPA* and the court did not discuss the Pyrolysis Unit Exemption or whether the existence of a thermal oxidizer to combust pyrolysis gases removes a pyrolysis system from the Pyrolysis Unit Exemption. The decision also did not discuss whether pyrolysis gases are HMIW as defined in the HMIWI Rule or are solid waste as used in Section 129. For these reasons Region IX's cannot rely on the decision to support its determination that Aemerge RedPak's pyrolysis system does not qualify for the Pyrolysis Unit Exemption or as a basis to disregard the SMS Determination. Instead, Region IX must either make a determination consistent with the SMS Determination or clearly articulate a reasonable rationale for deviating from Region 5 and OAQPS' SMS Determination that the Pyrolysis Unit Exemption includes a thermal oxidizer used to combust pyrolysis gases by distinguishing the SMS Determination. *See*, U.S. EPA Memorandum, "How to Review and Issue Clean Air Act Applicability Determinations and Alternative Monitoring" (February 1999), at p. 52 (If a previous determination seems to contradict our current determination, explain how the current case is different . . .).

Aemerge RedPak believes that the ET Determination and SMS Determination cannot be distinguished in a relevant manner from our situation and the Pyrolysis Unit Exemption should apply to Aemerge RedPak's pyrolysis system.

Region IX's Interpretation Inappropriately and Impermissibly Applies the HMIWI Rule to Pyrolysis Technologies.

Region IX's interpretation of the Pyrolysis Unit Exemption results in exactly what the Pyrolysis Unit Exemption was intended to avoid – the application of incinerator rules that are not designed or written to be applied to a pyrolysis system. At the time the HMIWI Rule was adopted, U.S. EPA acknowledged that pyrolysis technology is inherently different than incineration and found that “nearly all aspects of the HMIWI regulations would have to be altered to include pyrolysis units including the format of the emission limits, the operator training requirements, the siting requirements, the testing and monitoring requirements, and the reporting and record keeping requirements.” 62 Federal Register 48348, 48358-59 (September 15, 1997). U.S. EPA concluded: “Because regulations developed for HMIWI are not appropriate for pyrolysis technologies, pyrolysis treatment technologies have specifically been excluded from coverage under the final HMIWI standards and guidelines.” *Id.* at 48359.

The difficulty of forcing a pyrolysis system into rules written for conventional incineration units is illustrated by the HMIWI Rule definitions for primary chamber and secondary chamber. To meet the HMIWI Rule definition of “primary chamber,” the chamber must meet three conditions: (1) be the location where the waste material is received; (2) be the location where the waste is ignited; and (3) be the location where the ash is removed. Aemerge RedPak's pyrolysis chamber receives the waste; however, because the process is endothermic, there is no ignition of the waste. Because the waste is charged to the pyrolysis chamber rather than into the thermal oxidizer and there is no ash removed from the thermal oxidizer as only syngas goes to the thermal oxidizer, the thermal oxidizer does not meet the definition of a primary chamber.

The HMIWI Rule defines “secondary chamber” as “a component of the HMIWI that receives combustion gases from the primary chamber and in which the combustion process is completed.” The pyrolysis chamber also does not meet the definition of a “secondary chamber” because, as Region IX acknowledged, no combustion takes place in the pyrolysis chamber. The thermal oxidizer does not meet the definition of a secondary chamber because it does not receive combustion gases from the pyrolysis chamber.

The HMIWI Rule defines “maximum design waste burning capacity” in terms of the primary chamber volume. Because neither Aemerge RedPak's pyrolysis chamber nor the thermal oxidizer meet the definition of “primary chamber,” it is not possible to establish a maximum design waste burning capacity as defined by the HMIWI Rule at 40 CFR § 60.51c, which in turn is required in order to determine the applicable emission limits and other requirements.

Because the Aemerge RedPak pyrolysis system can perform in an environmentally and functionally superior manner to conventional incineration, it is expected to be able to meet the emission limitations in the HMIWI Rule. However, the improper imposition of the HMIWI Rule places inequitable operating limits on the Aemerge RedPak pyrolysis system that were never subject to proper rulemaking. Two examples are:

- Compliance with the applicable oxides of nitrogen (NO_x) limitation; and
- The oxygen dilution standard of 7% for emissions limitation compliance.

Like most pyrolysis technologies systems in the world today, the Aemerge RedPak pyrolysis system uses an oxidizer to combust the syngas produced by gasification of the pyrolyzed organic material. Unlike a medical waste incinerator, combustion of the syngas takes place in a high excess air environment where the temperature of the oxidizer is primarily controlled by induction of excess air to limit excessive combustion temperatures. This type of system is inherently lower in NO_x emissions than a multi-chamber incinerator. The HMIWI Rule sets a large HMIWI emissions limitation for NO_x of 140 ppmv at 7% oxygen. The Aemerge RedPak pyrolysis system will operate at less than 25 ppmv for NO_x. However, there is a tradeoff between destruction of carbon monoxide (CO) and formation of NO_x. Higher operating temperatures create higher NO_x emissions, but are more effective at destruction of CO.

The HMIWI Rule specifies an oxygen level for concentration-based emissions limitations in order to ensure that a facility does not use dilution of the stack gas to meet the limits. These specified oxygen limits are established as part of the regulatory review that establishes the emissions limitations for specific categories of equipment such as medical waste incinerators. Because the Aemerge RedPak pyrolysis system's thermal oxidizer component will operate at substantially higher oxygen levels than an incinerator, the actual stack emissions concentrations for the Aemerge RedPak pyrolysis system must be much lower than the HMIWI Rule standards. The HMIWI Rule's CO limit of 11 ppm effectively becomes 5.5 ppm after taking into account the oxygen adjustment from 14% to 7% oxygen in the actual stack gas. While the state-of-the-art Callidus thermal oxidizer employed in Aemerge RedPak's pyrolysis system can meet this lower effective limit, the oxygen-adjusted effective limit will pose substantial operational limits in order to comply on a continuous basis. Had U.S. EPA developed appropriate standard, testing, and monitoring requirements for a pyrolysis system, the result would have been a more stringent NO_x limit and a less stringent CO limit. U.S. EPA recognized this in the preamble to the HMIWI Rule:

“nearly all aspects of the HMIWI regulations would have to be altered to accommodate pyrolysis units including the format of the emission limits, the operator training requirements, siting requirements, the testing and monitoring requirements, and the reporting and recordkeeping requirements. Furthermore, the HMIWI subcategories and MACT floors would not be appropriate for pyrolysis units.”

62 Federal Register 48348, 48358-59 (September 15, 1997).

These difficulties further illustrate that the Pyrolysis Unit Exemption is intended to include the entire pyrolysis system, including the thermal oxidizer, in order to avoid the incongruous,

inequitable and inappropriate application of the HMIWI Rule. Region IX's interpretation is impermissible because as a practical matter it effectively removes the Pyrolysis Unit Exemption from the HMIWI Rule without first subjecting the removal of the Pyrolysis Unit Exemption to rulemaking that would be required, among other things, to establish MACT for pyrolysis systems. Required rulemaking may not be circumvented through the issuance of an applicability determination.

Pyrolysis Gases are Not HMIW.

Region IX's Determination acknowledged and agreed that the HMIW is destroyed in the pyrolysis chamber of Aemerge RedPak's pyrolysis system. *See* Determination at p. 4. However, Region IX asserted that the pyrolysis gases resulting from the destruction of HMIW are "gasified HMIW" and therefore the thermal oxidizer combusts HMIW. Region IX's characterization of the pyrolysis gas as HMIW is contrary to the U.S. EPA's definition of HMIW at 40 CFR § 60.51c as well as U.S. EPA guidance.

Neither the definition of "hospital waste" nor the definition of "medical/infectious waste" contain the words "gas" or "gases" or the terms "gasified waste" or "gasified HMIW." In the preamble to the 1997 HMIWI Rule, U.S. EPA made it clear that the definition of hospital waste is limited to only those wastes generated at a hospital. *See* 62 Federal Register at 48356 ("It should also be noted that 'hospital waste' is simply waste *generated at a hospital*." (emphasis added)). The pyrolysis gases are not generated at a hospital.

In the preamble to the 1997 HMIWI Rule, U.S. EPA explained that it was codifying the Medical Waste Tracking Act (MWTa) definition of regulated medical waste as the definition of "medical/infectious waste." *See* 62 Federal Register at 48355. The MWTa was enacted in response to public concerns over wash-ups of medical waste on beaches and reports of careless management of medical wastes. To address these concerns, the MWTa required U.S. EPA to develop rules to establish a medical waste tracking system in certain states. The MWTa and the MWTa rules did not include uncontained gaseous materials in the definition of medical waste. By using the MWTa definition, U.S. EPA limited the applicability of the HMIWI Rule to seven specific classes of medical/infectious wastes generated in the diagnosis, treatment or immunization of human beings or animals, in the research pertaining thereto, or testing or production of the listed biologicals. Neither the MWTa definition nor the HMIWI Rule definition use the words "gas" or "gases" or the terms "gasified waste" or "gasified HMIW." None of the items listed in the definition are uncontained gases. Because pyrolysis gases are not generated during the diagnosis, treatment or immunization of human beings or animals, related research or testing or production of biologicals, pyrolysis gases do not come within the definition of medical/infectious waste.

By adopting the MWTa rule's definition of regulated medical waste as the definition of "medical/infectious waste" in the HMIWI Rule, U.S. EPA also did not intend to include uncontained gaseous material in the definition of "medical/infectious waste." To have done so

U.S. EPA would have had to expressly add uncontained gaseous material to the list of regulated medical wastes it adopted in the HMIWI Rule; however, this would have been beyond the authority granted by Congress which unambiguously limited the RCRA definition of solid waste to contained gases.

Aemerge Redpak's pyrolysis chamber both treats and completely destroys the HMIW. A complete thermal conversion occurs within the pyrolysis chamber and the gases exiting the pyrolysis chamber are uncontained gaseous material that exhibit none of the chemical, infectious or physical characteristics of the HMIW that is fed into the pyrolysis chamber. The pyrolysis gases combusted by the thermal oxidizer do not meet the definition of HMIW.

There is nothing in the HMIWI Rule or rulemaking documents that supports Region IX's opinion that pyrolysis gases are HMIW. Consistent with its intent that pyrolysis gases are not HMIW, U.S. EPA never referred to pyrolysis gases as HMIW in the ET Determination, the SMS Determination, HMIWI Rule, or Draft MWP Rule. Indeed, U.S. EPA specifically recognized in the ET Determination that the wastes were kept segregated in the pyrolysis chamber, demonstrating that U.S. EPA did not consider the pyrolysis gases to be a waste. Because pyrolysis gases are not included in the definition of HMIW, Aemerge RedPak's thermal oxidizer does not meet the definition of an HMIWI unit because it not combusting HMIW, regardless of whether or not pyrolysis gases are a solid waste under Section 129. As shown below, however, because the pyrolysis gases are not contained gaseous material, such gases are not a solid waste.

Pyrolysis Gases are Not Solid Waste.

According to Section 129(g)(6) of the CAA, the term "solid waste" shall have the meaning established by U.S. EPA pursuant to the Solid Waste Disposal Act (commonly referred to as RCRA). The RCRA definition of solid wastes states:

"The term 'solid waste' means any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or *contained gaseous material* resulting from industrial, commercial, mining, and agricultural operations, and from community activities"

42 U.S.C. § 6903(27) (emphasis added). Medical waste is a subset of solid waste.

Under the statutory definition, a gas must be contained before it can be considered a solid waste. When applied to pyrolysis gases, U.S. EPA's longstanding interpretation of "contained gaseous material" means that the pyrolysis gases are not solid waste for purposes of Section 129.

U.S. EPA's position was initially established in 1982 during promulgation of regulations for hazardous waste incineration facilities. 47 Federal Register 27520 (June 24, 1982). In the preamble to this final rule, U.S. EPA stated:

“EPA agrees with commenters that fume incinerators are subject only to regulation under the Clean Air Act and does not intend that Parts 264 and 265 regulations apply to these facilities. Fume incinerators which are used to destroy gaseous emissions from various industrial processes, for example, are not subject to regulation under RCRA. In general the RCRA standards do not apply to fume incinerators since the input is not identifiable as solid waste, according to the definition set forth in § 261.2.”

47 Federal Register at 27530.

On several subsequent occasions U.S. EPA has reaffirmed its interpretation that uncontained gases are not within the RCRA definition of “solid waste.”

- In 1984 U.S. EPA stated that any incinerators which receive only gaseous emissions are not subject to RCRA. *See* Memorandum from John Skinner, OSW, to James Scarborough, U.S. EPA, Region IV (July 31, 1984), RO 12272.
- In 1986 U.S. EPA stated a fume incinerator used only to destroy gaseous emissions from an industrial process is not subject to RCRA regulation since the fume input, being an uncontained gas, is not a solid waste (per the June 24, 1982, Federal Register (47 FR 27530)). *See*, RCRA/Superfund Hotline Monthly Summary (March 1, 1986), RO 12568.
- In a 2011 letter to the American Forest and Paper Association, U.S. EPA stated:

“Thus, burning of gaseous materials, such as in fume incinerators (as well as other combustion units, including air pollution control devices that may combust gaseous material) does not involve treatment or management of a solid waste (as defined in RCRA section 1004(27)).”

Letter from Suzanne Rudzinski, Director, U.S. EPA Office of Resource Conservation and Recovery, to Tim Hunt, American Forest and Paper Association, May 13, 2011.

- In the final rule for reconsideration of the CISWI Rule, U.S. EPA codified the definition of “contained gaseous material” as meaning “gases that are in a container when that container is combusted.” 40 CFR § 60.2265. 78 Federal Register 9112 (February 7, 2013).
- In response to a comment on the CISWI rule seeking confirmation that synthesis gas or any gas not in a container is not a waste, U.S. EPA stated:

“We believe it is appropriate to include a definition for solid waste because only units combusting solid waste are subject to the

standards issued pursuant to section 129. The definitions of solid waste and contained gaseous material, taken together, mean that gaseous material is only a solid waste for purposes of CISWI if the material is in a container when the container is combusted.”

See, Summary of Public Comments and Responses for CISWI, at p. 314 (January 3, 2013) (EPA-HQ-OAR-2003-0119-2690).

Because the HMIWI Rule also was issued pursuant to Section 129 of the CAA and both the HMIWI Rule and CISWI rule are constrained by the same definition of solid waste, U.S. EPA’s interpretation of “contained gaseous material” as articulated in prior guidance and in the CISWI rule also applies to a determination of whether a unit is subject to the HMIWI Rule. There is no basis for defining contained gaseous material differently under the HMIWI Rule.

Region IX’s assertion that pyrolysis gases are gasified waste and therefore HMIW effectively undoes the U.S. EPA’s long-standing definition of the term “contained gaseous material.” Doing so would reignite uncertainty whether the large number of thermal oxidizers and flares used by industrial and commercial sources throughout the United States are solid waste incineration units subject to CISWI standards. Such an expansion of regulatory scope is inconsistent with long-standing U.S. EPA guidance, contrary to the definition of contained gaseous material as codified in the CISWI rule, and beyond the authority granted by Section 129 of the CAA.

On July 25, 2016 Region IX issued an applicability determination to Bioforcetech Corporation (BFT) finding that its pyrolysis reactor and oxidation burner are not subject to the sewage sludge incinerator (SSI) NSPS because the syngas generated by the pyrolysis reactor is not sewage sludge (BFT Determination). Region IX stated:

“The syn-gas is a gas and is not a solid, semi-solid or liquid. Therefore the syn-gas is not sewage sludge (even though it is derived from sewage sludge) as that term is defined in the SSI NSPS; therefore the FLOX® chamber is not combusting sewage sludge and therefore also not an SSI unit.”

By concluding the syngas was not sewage sludge, Region IX in effect also concluded that the syngas was not a solid waste; otherwise Region IX would have advised BFT that the combustion of the syngas made the unit subject to the CISWI NSPS (Having concluded the unit was not subject to the SSI NSPS, the BFT unit would not be able to claim the exemption from the CISWI NSPS for units subject to the SSI NSPS at 40 CFR § 60.2020(n)). Based on Region IX’s BFT Determination, the Bay Area Air Quality Management District (BAAQMD) concluded that BFT’s pyrolysis system is not subject to the CISWI NSPS. *See* BAAQMD Engineering Evaluation at pp. 9-10 (February 10, 2017). Region IX’s opinion that the pyrolysis gas generated by Aemerge RedPak’s pyrolysis chamber is gasified HMIW is inconsistent with the BFT Determination where Region IX did not find that pyrolysis gases are a solid waste subject to the CISWI NSPS.

Alexis Strauss
Acting Regional Administrator
January 8, 2018
Page 14

The pyrolysis gases entering Aemerge RedPak's thermal oxidizer are not in a container when combusted, and, therefore do not meet the definition of "contained gaseous material." For this reason the pyrolysis gases are not a solid waste. Because the pyrolysis gases are not a solid waste, the pyrolysis gases cannot be HMIW, a subset of "solid waste." Therefore, the thermal oxidizer does not meet the definition of a HMIWI because pyrolysis gases are neither a solid waste nor HMIW. Furthermore, Aemerge RedPak's facility is not subject to the CISWI rules because it does not combust solid waste and, therefore, it is not a "solid waste incineration unit" under Section 129 of the CAA and thus cannot be a CISWI as defined under 40 CFR § 60.2265.

Based on the foregoing and previously submitted information, Aemerge RedPak respectfully requests that Region IX issue a new applicability determination finding that Aemerge RedPak's pyrolysis system, including the thermal oxidizer, is covered by the Pyrolysis Unit Exemption, its facility is not subject to the HMIWI Rule and that its pyrolysis system, including the thermal oxidizer, is not a solid waste incineration unit under Section 129 of the CAA. Please contact me at lmiller@aemerge.com or Walter Koucky, Cornerstone EH&S, at wkoucky@corner-enviro.com if you need further information or copies of any referenced materials. Thank you for your consideration.

Sincerely,

AEMERGE REDPAK SERVICES SOUTHERN CALIFORNIA, LCC

Landon Miller, COO

cc: Matt Salazar, U.S. EPA Region IX (Salazar.Matt@epa.gov)
Roshni Brahmbatt, U.S. EPA Region IX (Brahmbatt.Roshni@epa.gov)
Marcia Mia, U.S. EPA (Mia.Marcia@epa.gov)
Adam Seger, President and CEO, Aemerge RedPak
Walter F. Koucky, M.S., Cornerstone EH&S (wkoucky@corner-enviro.com)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IX

75 Hawthorne Street
San Francisco, CA 94105-3901

OFFICE OF THE
REGIONAL ADMINISTRATOR

Landon Miller
Aemerge RedPak Services Southern California, LLC
9600 E Avenue
Hesperia, California 92345

APR 07 2017

Re: Applicability determination of 40 CFR Part 60, Subpart Ec – Standards of Performance for New Stationary Source: Hospital/Medical/Infectious Waste Incinerators to proposed project by Aemerge RedPak Services Southern California, LLC

Dear Mr. Miller,

This letter responds to your request, via email to Matt Salazar of my staff, for an applicability determination as referenced above. Aemerge is proposing construction of a system in Hesperia, CA for the destruction of hospital/medical/infectious waste (HMIW). Based on the information you provided to us, the EPA has determined that the exemption at 40 C.F.R. 60.51c in 40 CFR Part 60, Subpart Ec (HMIWI standards) for "any pyrolysis unit" would not apply to the Aemerge system. Furthermore, if constructed and operated as described, the system would be subject to the HMIWI standards.

EPA Response

In your letter, you provide the following information about the proposed project:

1. The Aemerge system consists of three components:
 - a. Carbonizer
 - b. Thermal Oxidizer
 - c. Heat recovery steam generator
2. The first component within the system, the Aemerge carbonizer unit, is described as an inert gas "carbonization" process; i.e., the culmination of pyrolysis where carbonaceous material is converted to elemental carbon by reduction (the opposite of oxidation).
3. The Aemerge carbonizer unit is designed to process 5,800 pounds per hour of medical waste.

4. The Aemerge carbonizer unit is endothermic.¹
5. The waste processed in the Aemerge carbonizer unit² is contained in a sealed chamber (muffle) that receives indirect heat from an outer jacket that can be heated with natural gas or electric heat. The outer jacket is completely isolated from the inner muffle.
6. The Aemerge carbonizer unit uses nitrogen to blanket the waste material as it travels down the muffle by way of the drag chain. The nitrogen blanket and negative pressure in the muffle are designed to eliminate combustion and combine with high pyrolytic heat from the outer jacket to drive off volatiles from the waste in the carbonizer unit.
7. The intent of the design of the Aemerge carbonizer unit is to produce a high quality carbon with minimal ash. Example products are carbon that can be used as pigment for black coloration and char that can be charged with nutrient for landscape application.
8. The Aemerge carbonizer unit also will generate a synthetic gas (syngas), the composition of which will be largely methane.
9. The syngas then will be combusted in the second component of the Aemerge system - the thermal oxidizer.
10. The resultant heat from the thermal oxidizer is used in the third component of the system - the heat recovery steam generator (HRSG).³
11. Based on the construction date, if subject to the HMIWI standards, the applicable units comprising the Aemerge system would be a new source.

In accordance with §60.50c, the affected facility to which the HMIWI standards apply is each individual HMIWI constructed, in relevant part, after December 1, 2008. HMIWI is defined at §60.51c as “any device that combusts any amount of hospital waste and/or medical/infectious waste.” Aemerge provides that the system as a whole will be used to destroy hospital, medical, and infectious waste, and will be constructed after December 1, 2008.

There is an exemption at §60.50c(f) for “any pyrolysis unit” where the term “pyrolysis” is defined at §60.51c as the “endothermic gasification of hospital waste and/or medical/infectious waste using external energy.”⁴

¹ You state that the Aemerge “unit” is endothermic. We assume you mean the carbonizer unit within the three-component system, as later in the letter you discuss the use of heat recovery after the oxidizer, the third and second components of the system, respectively (Background Item 10). Heat recovery would not be possible in an endothermic unit, as there would be no heat generated.

² Again, we read “unit” to mean only the carbonizer component.

³ You state that you also intend to evaluate cleaning of the syngas and use of the syngas in internal combustion electrical generation. Pursuant to §129(g)(1) of the Clean Air Act, the term “solid waste incineration unit,” in relevant part, does not include qualifying small power production facilities, as defined in section 796(17)(C) of title 16, or qualifying cogeneration facilities, as defined in section 796(18)(B) of title 16, which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy. Since this was not presented to the EPA as a current option, we are not evaluating that scenario.

⁴ The EPA discussed pyrolysis in the June 20, 1996, re-proposal for the HMIWI standards (see 61 FR 31736) and concurrently developed a draft regulation for pyrolysis units (see Legacy Air Docket A-91-61, Item IV-B-56). In the September 15, 1997, final rule (see 62 FR 48348) the EPA deferred on developing standards for pyrolysis units and determined that the HMIWI standards were not appropriate for pyrolysis units. Subsequently, the exemption and definition of “pyrolysis unit” were promulgated at §§60.50c(f) and 60.51c, respectively.

We do not believe that the exemption for “any pyrolysis unit” is applicable to the three-component Aemerge system. In the information you provided, the process in the carbonizer unit has been described as an endothermic “pyrolysis” process; however, the carbonizer, thermal oxidizer, and heat recovery steam generator operate as a multi-component system and therefore we must evaluate each of them as part of a system. This is because the gas stream generated in one component (the carbonizer) is immediately and continuously routed to the next component (the thermal oxidizer), and the operation of the prior carbonizer is integral to the operation of the subsequent oxidizer. Emissions are not emitted to the atmosphere until the gases have passed through all three components, including the heat recovery steam generator. Some of the units, according to your information, are endothermic (e.g., the carbonizer), while some are exothermic (e.g. the thermal oxidizer). Therefore, because the Aemerge system is not “endothermic” throughout its system, we do not believe that the Aemerge system meets the exemption for “any pyrolysis unit” as “pyrolysis” is defined in the HMIWI standards. However, this alone does not mean that the system is therefore subject to the HMIWI standards.

Section §60.51c of Subpart Ec “Definitions” states that a hospital/medical/infectious waste incinerator or HMIWI or HMIWI unit means:

any device that combusts any amount of hospital waste⁵ and/or medical/infectious waste.⁶

⁵ *Hospital waste* means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and anatomical parts that are intended for interment or cremation. See §60.51c.

⁶ *Medical/infectious waste* means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that are listed in paragraphs (1) through (7) of this definition. The definition of medical/infectious waste does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as defined in §261.4(b)(1) of this chapter; ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment or cremation; and domestic sewage materials identified in §261.4(a)(1) of this chapter.

(1) Cultures and stocks of infectious agents and associated biologicals, including: Cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

(2) Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

(3) Human blood and blood products including:

(i) Liquid waste human blood;

(ii) Products of blood;

(iii) Items saturated and/or dripping with human blood; or

(iv) Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in

As provided by Aemerge, the system receives HMIW. The gas produced by the destruction of the HMIW in the carbonizer unit is routed to the thermal oxidizer (the second component of the system) where the synthetic gases resulting from the gasification of HMIW are then combusted. This meets the definition of a HMIWI - a "device that combusts any amount of hospital waste and/or medical/infectious waste" - as the rule does not exclude gasified HMIW. In fact, in the February 27, 1995, proposed rule, we describe a typical HMIWI design system:

sequential combustion operations typically are carried out in two separate chambers: primary and secondary. In the primary chamber, the waste is loaded and ignited, *the volatile organic components driven off*, and the nonvolatile materials combusted to ash. The volatile organic components released from the primary chamber are combusted in the secondary chamber. [Emphasis added]

While the muffle furnace and nitrogen blanket should not allow for ignition of the waste in the carbonizer unit of the Aemerge system, the purpose of that step is to drive the volatile organic components off to the next component, the thermal oxidizer, where those volatile organic components are then combusted. See "Background Item 6," above: "[t]he nitrogen blanket and negative pressure in the muffle are designed to eliminate combustion and combine with high pyrolytic heat from the outer jacket *to drive off volatiles.*"

Therefore, as the syngas produced by the destruction of the HMIW is combusted by the thermal oxidizer within the overall Aemerge system, we conclude that the Aemerge system is combusting HMIW and is consequently subject to 40 CFR Part 60 Subpart Ec.

As a HWIMI, it does not appear from the information provided that the Aemerge system meets 40 CFR Part 241 standards for determining that a non-hazardous secondary material (NHSM) is a non-waste. To be considered a non-waste, a NHSM must be processed into a legitimate

either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.

(4) Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

(5) Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.

(6) Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

(7) Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades. See §60.51c.

product fuel prior to introduction into the combustion unit. We are happy to speak to you further about application of the NHSM standards to your system.

In your letter, and subsequent email of February 22, 2016, you provided examples of previous determinations relating to gasification, pyrolysis, and combustion and applicability under section 129, including under section 129 rules other than the HMIWI standards. We note that each determination of applicability is made on a case “by” case basis and is specific to the source and rule in question. This determination is not based on any re-evaluation of the examples you provided, but is based on the information you provided regarding that Aemerge system in comparison with the provisions of the HMIWI standards governing the rule’s applicability.

Your letter presented seven (7) statements as rationale for your position that “EPA has stated that gasification is a chemical process and is not a combustion process” and “therefore not subject to regulation under the authority of Section 129 of the CAA, which regulates solid waste combustion.” We respond to those statements below:

Aemerge Statement 1:

A 1995 EPA Office of Solid Waste memorandum concludes that a unit that “operates outside of the limits of flammability” “is not an incinerator.”

EPA Response:

CAA Section 129 does not define combustion nor do any of the underlying regulations promulgated pursuant to section 129. We evaluate applicability based on the specific rule’s regulatory applicability provisions, as well as the technical support documents which were used to develop the standards, in comparison to the facts presented in a specific case. General statements that may have been issued for other purposes do not compel specific applicability determinations under section 129.

Aemerge Statements 2 and 3:

In response to comments on the Commercial/Industrial Solid Waste Incineration Rule (CISWI), EPA reiterated the position made in the Non-Hazardous Secondary Materials (NHSM) Rule – essentially that gas is not a solid waste, except in the rare case that it becomes containerized.

EPA Responses 2 and 3:

The characterization by Aemerge oversimplifies NHSM and “contained gas.” A gas may be a solid waste subject to section 129, unless the particular rule explicitly were to exempt it from the rule’s scope. Furthermore, based on the facts presented to us so far, we do not believe that “contained gas” needs to be explored for the Aemerge system, for the reasons described above; i.e., the three chambers operate as a system to combust gas produced by the destruction of the HMIW, thus meeting the definition of a HMIWI - a “device that combusts any amount of hospital waste and/or medical/infectious waste.”

Aemerge Statement 4:

Section 129 of the CAA applies to solid waste incineration units where the term “solid waste incineration unit” means “a distinct operating unit of any facility which combusts any solid waste material from commercial or industrial establishments or the general public.”

EPA Response 4

We agree with this general statement; however, it does not support concluding that the Aemerge system is not a HMIWI, as the system both contains a component that in fact combusts waste gases and as a whole serves that purpose.

Aemerge Statement 5:

Aemerge asserts that EPA’s information on the Gasification Rule⁷ states EPA’s position that gasification is a chemical process and is not combustion. As gasification is not combustion, gasification units cannot be combustion units regulated under Section 129 of the Clean Air Act.

EPA Response 5:

EPA notes that the Gasification Rule was vacated and subsequently re-promulgated without an exemption for gasification. See 80 FR 18777. Irrespective of that vacatur, EPA agrees that gasification alone is not combustion. However, for the reasons discussed in the body of this letter, we do not believe that the Aemerge system is comprised of gasification alone, but in fact involves a component (and therefor an overall system) that combusts HMIWI.

Aemerge Statement 6:

In the December 19, 2013, letter from the EPA to MaxWest, EPA determined that neither the gasification, nor the oxidation of the syngas was regulated under the sewage sludge incinerator (SSI) standard for that facility.

EPA Response 6:

The determination of applicability of the SSI standards to MaxWest does not pre-judge the determination of applicability of the HMIWI rule to Aemerge. We note, moreover, that the applicability and definitions of the types of units in the SSI standards and the HMIWI standards are different. For example, the SSI rule limits the definition of sewage sludge to liquid, solid, or semi-solid forms of the waste, which HMIWI does not.

Aemerge Statement 7:

EPA used the overall net energy input as the criteria regarding the definition of “pyrolysis unit” in the HMIWI rule when determining the applicability of the HMIWI standards to a facility owned by Statewide Medical Services.

⁷ Aemerge refers to the 2008 Final Rule regarding the Regulation of Oil-Bearing Hazardous Secondary Materials from the Petroleum Refining Industry Processed in a Gasification System To Produce Synthesis Gas as the “Gasification Rule.” See 73 FR 57.

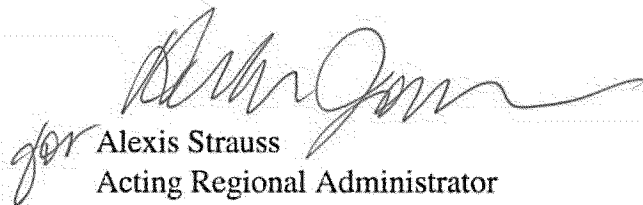
EPA Response 7:

Although we are not revisiting previous determinations of applicability for the purposes of this response, we note that the determination you mentioned predates promulgation of the NHSM rule and the ruling in *NRDC v. EPA*, 489 F.3d 1250 (DC Cir. 2007) (“NRDC”). The court stated that section 129 unambiguously requires any unit that combusts “any solid waste material at all” to be regulated as a “solid waste incineration unit.” *Id.* For the reasons discussed in the body of the letter, we believe that the Aemerge system combusts HMIW and does not meet the exemption for any “pyrolysis unit.”

This determination is based on the information provided by Aemerge to the EPA. Should any of the facts change, a new applicability determination may need to be made. This determination was coordinated with the Office of Air Quality Planning and Standards, the Office of Enforcement and Compliance Assurance, the Office of General Counsel and EPA Region IX.

Thank you for your request and for the information you included about your proposed project. If you have any questions about our response, please contact my staff, Roshni Brahmhatt, at (415) 972-3995.

Sincerely yours,


for Alexis Strauss
Acting Regional Administrator

To: Lannen, Justin[Lannen.Justin@epa.gov]; Smith, Suzanne[Smith.Suzanne@epa.gov]
Cc: Murdock, Russell[Murdock.Russell@epa.gov]; Olszewski, Joshua[olszewski.joshua@epa.gov]
From: Welton, Patricia[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=04374B1A19E84BB88C61FAC683D9CA12-WELTON, PATRICIA]
Sent: Fri 11/9/2018 3:11:27 PM (UTC)
Subject: Fwd: Aemerge RedPak Applicability Determination
Aemerge RedPak Applicability Determination 2018_10_31.pdf
ATT00001.htm

Begin forwarded message:

From: "Larson, Darrin" <Larson.Darrin@epa.gov>
Date: November 7, 2018 at 9:42:15 AM CST
To: "Welton, Patricia" <Welton.Patricia@epa.gov>
Subject: FW: Aemerge RedPak Applicability Determination

Heads up – call me for more info.

Darrin Larson
Chief, Air Permitting Enforcement Section (6EN-AA)
U.S. EPA Region 6
Office: 214-665-7115
Mobile: 972-467-5509

From: Kaleri, Cynthia
Sent: Wednesday, November 07, 2018 9:24 AM
To: Thompson, Steve <thompson.steve@epa.gov>; Larson, Darrin <Larson.Darrin@epa.gov>
Subject: FW: Aemerge RedPak Applicability Determination

Fyi

From: Mia, Marcia
Sent: Tuesday, November 6, 2018 11:01 AM
To: Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: FW: Aemerge RedPak Applicability Determination

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

This message may contain deliberative, attorney-client or otherwise privileged material. Do not release this message without the appropriate review. If you are not the intended recipient, kindly advise and delete this message/attachments.

From: Dancher, Nathan
Sent: Wednesday, October 31, 2018 9:33 PM
To: lmiller@AEMERGEREDPAK.COM
Cc: ABowman@bgdlegal.com; aseger@AEMERGEREDPAK.COM; Mia, Marcia <Mia.Marcia@epa.gov>; Modak, Nabanita <Modak.Nabanita@epa.gov>; Thrift, Mike <thrift.mike@epa.gov>; Hambrick, Amy <Hambrick.Amy@epa.gov>; Jones, Joel E. <Jones.Joel@epa.gov>; Salazar, Matt <Salazar.Matt@epa.gov>
Subject: Aemerge RedPak Applicability Determination

ED_006024A_00003449-00001

Landon,

Please see attached for EPA's letter responding to your January 8, 2018 request for reconsideration of the applicability determination issued to Aemerge RedPak. If you have any further questions, please let us know.

Thank you,
Nathan

Nathan Dancher
U.S. Environmental Protection Agency - Region 9
Enforcement Division
Air and TRI Section (ENF 2-1)
415-972-3482
Dancher.Nathan@epa.gov

To: Welton, Patricia[Welton.Patricia@epa.gov]; Lannen, Justin[Lannen.Justin@epa.gov]
From: Larson, Darrin[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AF2D4B28B0B842B2BAF3DF180786B67E-LARSON, DARRIN]
Sent: Thur 2/28/2019 3:25:59 PM (UTC)
Subject: FW: Monarch -- UPDATE
Monarch MWT Briefing Sheet 02-28-2019.docx

Darrin Larson
Chief, Air Permitting Enforcement Section (6EN-AA)
U.S. EPA Region 6
Office: 214-665-7115
Mobile: 972-467-5509

From: Larson, Darrin
Sent: Thursday, February 28, 2019 9:25 AM
To: Cheryl Seager <Seager.Cheryl@epa.gov>
Cc: Steve Thompson <thompson.steve@epa.gov>
Subject: Re: Monarch -- UPDATE

Here's an update of the paragraph in last week's WAR and updated briefing sheet.

On February 22, 2019, Monarch Waste Technologies completed initial performance testing at its hospital/medical/infectious waste incinerator located on the Nambe Pueblo near Santa Fe, New Mexico. EPA is currently waiting to receive the testing reports. Monarch began the test in December but due to operational issues was not be able to complete it. The test was conducted under an Administrative Compliance Order on Consent that Monarch entered into with EPA on December 4, 2018, which was modified on December 21, 2018. The Order allowed Monarch to startup and operate the unit for the purpose of completing the initial performance test after it lost the authority to operate because it did not submit a complete operating permit application within twelve months of commencing operations. Monarch was unable to submit a complete Title V permit application because required elements of a complete permit application—completion of initial performance testing and reporting of the test results—were not done. The incinerator is on the Nambe Pueblo, and EPA has provided updates on the status of the performance test to the Nambe Pueblo government.

Darrin Larson
Chief, Air Permitting Enforcement Section (6EN-AA)
U.S. EPA Region 6
Office: 214-665-7115
Mobile: 972-467-5509

From: Thompson, Steve
Sent: Thursday, February 28, 2019 9:08 AM
To: Larson, Darrin <Larson.Darrin@epa.gov>
Cc: Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: Fwd: Monarch -- UPDATE

Can you craft a quick update?

Sent from my iPhone
Begin forwarded message:

From: "Seager, Cheryl" <Seager.Cheryl@epa.gov>
Date: February 28, 2019 at 8:48:28 AM CST
To: "Thompson, Steve" <thompson.steve@epa.gov>
Cc: "Gilrein, Stephen" <gilrein.stephen@epa.gov>
Subject: FW: Monarch -- UPDATE

-----Original Message-----

From: Gray, David
Sent: Thursday, February 28, 2019 7:21 AM
To: Stenger, Wren <stenger.wren@epa.gov>; Idsal, Anne <idsal.anne@epa.gov>; Chancellor, Erin <chancellor.erin@epa.gov>; Seager, Cheryl <Seager.Cheryl@epa.gov>
Cc: Price, Lisa <Price.Lisa@epa.gov>; Turk, James <turk.james@epa.gov>
Subject: RE: Monarch -- UPDATE

Can I get an update on Monarch?

-----Original Message-----

From: Stenger, Wren
Sent: Wednesday, December 19, 2018 4:12 PM
To: Idsal, Anne <idsal.anne@epa.gov>; Chancellor, Erin <chancellor.erin@epa.gov>; Seager, Cheryl <Seager.Cheryl@epa.gov>; Gray, David <gray.david@epa.gov>
Cc: Stenger, Wren <stenger.wren@epa.gov>; Price, Lisa <Price.Lisa@epa.gov>
Subject: Monarch -- UPDATE

Monarch is still fishing for a "completeness" determination. We again advised them we could not provide that without the completion of the performance testing and the final OPLs/performance test data demonstrating compliance.

REGION 6 EXECUTIVE SUMMARY
Compliance Assurance and Enforcement Division

TOPIC: Monarch Waste Technologies – Hospital/Medical/Infectious Waste Incinerator

DATE: February 28, 2019

CONTACT: Steve Thompson, 6EN-A

PURPOSE/ACTION NEEDED: Update – Performance Testing under Administrative Order

ACTION DATE: NA

BACKGROUND:

Monarch Waste Technologies, LLC (Monarch) has constructed a commercial facility on the Nambé Pueblo near Santa Fe, New Mexico, to destroy hospital, medical, and infectious wastes. In its October 2016 request to EPA Region 6 for an applicability determination, Monarch asserted that its Pyromed 550 System met the pyrolysis exclusion in the New Source Performance Standard (NSPS) for Hospital/Medical/Infectious Waste Incinerators (HMIWI) (Subpart Ec). Monarch believe that if it met the exclusion, the facility would not be regulated by any NSPS and would not be required to obtain a Title V operating permit.

In June 2017, Region 6 told Monarch that EPA was prepared to issue a formal applicability determination (final agency action) concluding that NSPS Subpart Ec is applicable to the facility. Monarch subsequently withdrew its request and indicated to Region 6 that it planned to comply with NSPS Subpart Ec. On October 31, 2017, Region 6 conditionally approved Monarch's petition for site-specific operating parameters for the air pollution control equipment to be used at the facility, requiring submittal of a comprehensive Initial Performance Test plan and updated Waste Management Plan prior to testing. Monarch commenced commercial operations on November 20, 2017. However, Monarch immediately experienced an equipment failure, shut down the facility for repairs, and did not begin operating again for several months.

On December 7, 2017, Region 6 Air Permits requested that Monarch provide a Title V operating permit application by June 1, 2018 (40 C.F.R. § 71.5). Region 6 Air Permits subsequently extended the application submittal due date to September 1, 2018, based on a request from Monarch for additional time. Region 6 Air Permits notified Monarch on November 19, 2018, that, because the company did not submit a complete operating permit application as required within twelve months of commencing operation, Monarch no longer had authority to operate.

Monarch has been unable to submit a complete Title V permit application because required elements of a complete permit application, i.e. completion of initial performance testing and reporting of the test results, have still not been done. After months of working with the company on an acceptable test plan, Monarch submitted a revised test plan on November 15, 2018, which EPA approved on November 19, 2018.

CURRENT STATUS:

EPA and Monarch signed an Administrative Compliance Order on Consent on December 4, 2018, that authorized Monarch to operate for the limited purpose of preparing for and conducting an initial



Workforce Diversity, **E**nvironmental Stewardship **C**haracter, **A**ccountability, **R**espect, **E**xcellence

performance test. After Monarch was unable to stabilize incinerator operations and conduct a representative test in mid-December, EPA and Monarch modified the Order on December 21, 2018, to extend the deadline for completing the test to March 6, 2019. Monarch completed the testing on February 22, 2019, and EPA is awaiting the testing reports.

Monarch is also seeking an agency response on its updated applicability determination request regarding the Pyromed 550 System, which it sent to the Office of Enforcement and Compliance Assurance on December 9, 2018. The request states that Monarch believes the system should be exempt from NSPS Subpart Ec. Region 6 and OECA are reviewing the documents provided and preparing a response.

COMMUNITY CONCERNS:

There is significant interest from the Nambe Pueblo and NMED in ensuring that the facility operates effectively and safely given Monarch's plans to destroy infectious materials. Other Pueblo governments near the facility have expressed concern about operations and inquired about the status of the Title V Permit.

RECOMMENDATIONS:

None at this time.



Workforce Diversity, **E**nvironmental Stewardship **C**haracter, **A**ccountability, **R**espect, **E**xcellence

To: Lannen, Justin[Lannen.Justin@epa.gov]
From: Olszewski, Joshua[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FF460C25B7424C6E94A005774580DA6F-OLSZEWSKI, JOSHUA]
Sent: Thur 8/8/2019 3:29:00 PM (UTC)
Subject: FW: MWT Follow-Up

From: Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Sent: Thursday, August 08, 2019 10:20 AM
To: Robinson, Jeffrey <Robinson.Jeffrey@epa.gov>; Braganza, Bonnie <Braganza.Bonnie@epa.gov>; Olszewski, Joshua <olszewski.joshua@epa.gov>
Subject: FW: MWT Follow-Up

FYI – we definitely know how David’s mind works...

Cynthia J. Kaleri
Chief, Air Permits Section (ARPE)
Air Permits Monitoring & Grants Branch
Air and Radiation Division
214-665-6772 (office phone)

From: Mia, Marcia <Mia.Marcia@epa.gov>
Sent: Thursday, August 8, 2019 8:44 AM
To: Scinta, Robert <scinta.robert@epa.gov>; Duffy, Rick <Duffy.Rick@epa.gov>; Segall, Martha <Segall.Martha@epa.gov>
Cc: Larson, Darrin <Larson.Darrin@epa.gov>; Thompson, Steve <thompson.steve@epa.gov>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: FW: MWT Follow-Up

FYI.
Cindy, even though you have moved on – thought you would be interested in this.
Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

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From: Traylor, Patrick <traylor.patrick@epa.gov>
Sent: Thursday, August 08, 2019 9:30 AM
To: Mia, Marcia <Mia.Marcia@epa.gov>
Subject: FW: MWT Follow-Up

Full set of correspondence yesterday with Monarch, for your records. I explained to David exactly what you explained to him and told him that you and I were on exactly the same page.

When I told David that the company’s question had received the highest level attention, I meant him to understand that continuing to elevate his questions wouldn’t have any effect. He misunderstood and thought that the EPA was “supporting and approving” the company’s product. So you see my response for the record that we can’t approve or endorse a product.

Patrick Traylor
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
202.809.8796 (m)
202.564.5238 (o)

From: Rick Santorum <rick@ricksantorum.com>

Sent: Wednesday, August 7, 2019 10:06 PM

To: Traylor, Patrick <traylor.patrick@epa.gov>

Cc: David Cardenas <davidc@monarchwastetechnologies.com>; Jeff Blackard (blackard.net) <jblackard@blackard.net>

Subject: Re: MWT Follow-Up

Thank you and Administrator Wheeler!

Rick Santorum

On Aug 7, 2019, at 8:45 PM, Traylor, Patrick <traylor.patrick@epa.gov> wrote:

Thanks, David. I think it's important for me to say that your company's questions have gotten attention at the highest levels of the agency and that I have personally briefed Administrator Wheeler on the outcome of the June letter. Of course, the EPA cannot approve or endorse a particular technology.

Patrick Traylor

Deputy Assistant Administrator

Office of Enforcement and Compliance Assurance

U.S. Environmental Protection Agency

(202) 564-5238 (office)

(202) 809-8796 (cell)

On Aug 7, 2019, at 7:12 PM, David Cardenas <davidc@monarchwastetechnologies.com> wrote:

Thank you Patrick! I will proceed with State regulators on sites in the pipeline as we discussed using the Exemption Letter we received as it was written. Our dialogue today was very helpful for me to understand your approach and the intended audience it was focused towards (seasoned regulators) as they should be able to understand by default that our units are not applicable to the HMIWI Ec regs regardless if the Letter says Pyrolysis or not.

In the rare case if a State regulator should question something on applicability going forward, as I said, I will reach out to you directly to help shore up any disconnections on their part. You made an opening remark to me that is still ringing in my head "our technology has garnered the full attention, support and approval of the highest people at the EPA including Director Wheeler and yourself"! This statement was not taken lightly by any means and we appreciate you taking the time to say it.

On behalf of myself, my Partner Kevin, my friend Senator Santorum and Jeff we thank you for all your time and future support as we move forward in developing sites throughout the US in the coming years to solve the environmental issues at hand.

All my best,

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

Albuquerque Office 505.884.0995 Main

8501 Washington St. NE | Albuquerque | NM 87113

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www.monarchwastetechnologies.com

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From: Traylor, Patrick <traylor.patrick@epa.gov>

Sent: Wednesday, August 7, 2019 4:16 PM

ED_006024A_00003481-00002

To: Jeff Blackard <jblackard@blackard.net>
Cc: David Cardenas <davidc@monarchwastetechnologies.com>; Rick Santorum
<rick@ricksantorum.com>
Subject: RE: MWT Follow-Up

Mr. Blackard:

Thank you for these materials. I just got off the phone with Mr. Cardenas. I believe that he and I are in agreement that the EPA's June 2019 letter answers the company's most important question relating to the applicability of Subpart Ec.

Please let me know if you have any further questions.

Warm regards,
Patrick

Patrick Traylor
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
202.809.8796 (m)
202.564.5238 (o)

From: Jeff Blackard <jblackard@blackard.net>
Sent: Wednesday, August 7, 2019 3:58 PM
To: Traylor, Patrick <traylor.patrick@epa.gov>
Cc: David Cardenas <davidc@monarchwastetechnologies.com>; Rick Santorum
<rick@ricksantorum.com>
Subject: FW: MWT Follow-Up

<image006.png>

Jeffory D. Blackard
President & CEO • Blackard Global, Inc.
401 Adriatic Parkway, Suite 700, McKinney TX 75072
m: 214-914-1695 | w: blackard.net | w: neoretroism.com

From: Rick Santorum <rick@ricksantorum.com>
Date: Wednesday, August 7, 2019 at 2:56 PM
To: "traylor.patrick@epa.gov" <traylor.patrick@epa.gov>
Cc: Jeff Blackard <jblackard@blackard.net>
Subject: Re: Monarch Waste Technologies

Patrick

If there is anything I can do to help move this process, please let me know.

Thank you.

Rick Santorum

From: David Cardenas
Sent: Tuesday, August 6, 2019 9:57 PM
To: 'Jeff Blackard' <jblackard@blackard.net>
Subject: FW: MWT Follow-Up

Senator Santorum / Jeff, nice catching up with you guys the other day and thanks for your help to expand our efforts now that we have passed all of our tests proving we are 52% cleaner than an Incinerator which burns Medical Waste under Ec HMIWI standards!

Attached is the letter we received and the email I referred below that we need help to understand since we are now being asked to submit yet another exemption request, which would be the 4th request in the last 5 years! Not sure why we are being sent back to the beginning after we completed and passed everything exactly as we were asked. Simply put, if we are forced to go through another permitting beating like we did (still are-Title V) in Nambe on every site forward, our permitting costs and time line alone would economically kill the 15 sites we currently have in the pipeline in several States at the request of large Hospital systems (including Waste Management) to provide a clean solution in replacement of old incinerators.

Let me know your thoughts at your earliest since we have exhausted all options to secure the Exemption.

All the best,

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

Albuquerque Office 505.884.0995 Main

8501 Washington St. NE | Albuquerque | NM 87113

—
www.monarchwastetechnologies.com

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From: Mia, Marcia <Mia.Marcia@epa.gov>
Sent: Thursday, June 20, 2019 12:46 PM
To: David Cardenas <davidc@monarchwastetechnologies.com>; Scinta, Robert <scinta.robert@epa.gov>; Thrift, Mike <thrift.mike@epa.gov>
Subject: RE: MWT Follow-Up

Hi David,

Thanks for reaching out with your questions. I wanted to summarize what we discussed in our call today. Please let me know if I misstated anything.

1. You referenced the third paragraph of our 06/05/19, letter and asked if there is another cited authority which could provide a broad applicability determination (AD). I explained that AD's by definition are site specific, so no, there is not another authority that you might reference to receive a broad applicability determination.
2. You referenced footnote 3 of our letter ("The location of the "medical waste processing facility" is not identified") and pointed out that while your incoming request letter of 12/18 didn't specify the Nambe facility, the SNL test was conducted at that facility, so EPA should be able to use the Nambe facility for a site specific determination. I explained that you did not ask for a site specific determination for the Nambe facility. If you desire a site specific determination for the Nambe facility, you may request one from R6.

3. You believe that the letter only told you what you “aren’t” but not what you “are”. I don’t believe there was a question here, but I explained that we believe that EPA answered the questions you asked in your letter. If you have additional questions, or believe we did not answer the ones you asked in your letter, I suggested that you submit another letter.
4. You asked about footnote 5 (“If the unit is not a HMIWI, then we do not need to examine the exemption for pyrolysis units”) and wanted to know what that meant. I explained that it means that if your unit is not of the type regulated, then we don’t need to examine exemptions. I used the example of a rule that exempted “red HMIWI.” If you have a red widget maker, then we only need to know the widget maker isn’t a HMIWI. We don’t also need to decide if it is red, because the rule doesn’t apply in the first instance.

I hope the call, and this email summarizing our conversation, is helpful.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

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-----Original Appointment-----

From: Mia, Marcia
Sent: Wednesday, June 19, 2019 12:04 PM
To: Mia, Marcia; David Cardenas; Scinta, Robert; Thrift, Mike
Subject: MWT Follow-Up
When: Thursday, June 20, 2019 1:00 PM-1:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-855-564-1700; 1107219; Option 2: 234567

Adding a conference line.

To: Lannen, Justin[Lannen.Justin@epa.gov]
From: Olszewski, Joshua[O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FF460C25B7424C6E94A005774580DA6F-OLSZEWSKI, JOSHUA]
Sent: Wed 7/17/2019 9:16:28 PM (UTC)
Subject: FW: Monarch Title V
[Monarch-3.png](#)
[Monarch WE CARE Status Update 5-30-19 \(cyn input\).docx](#)
[Briefing for final permit issuance 3-20-19.docx](#)
[PyroMed 550 Process Flow and narrative revised 3-14-19.pdf](#)

From: Braganza, Bonnie
Sent: Wednesday, July 17, 2019 10:34 AM
To: Olszewski, Joshua <olszewski.joshua@epa.gov>
Cc: Robinson, Jeffrey <Robinson.Jeffrey@epa.gov>
Subject: Monarch Title V

Hello Josh:

Glad to hear you are my RC for this title V permit. Please see the briefing sheet that will give you some history of the facility with EPA that has not been vetted by management, but I use it as a guide for the SOB for the Title V permit. This briefing was condensed for management in May 20i9 and is also attached.

Please note the location of the facility, since there are occupied buildings within 1000 ft of the stack.

The new redesign of the facility is attached. EN is still waiting for one piece of information before they give the OK to the tests that were required within 6 months of startup. They need to know the actual feed rate during the various tests.

I had written some draft permits last year, but since the facility has been redesigned around the pyrolysis chamber to meet the Ec regulations, I will start from scratch. Hopefully I will have something for you to review next week.

Bonnie Braganza P.E
R6 ARPE
214-665-7340



REGION 6 EXECUTIVE SUMMARY

TOPIC: Monarch Waste Technologies Status

DATE: May 21, 2019

CONTACT: Cynthia Kaleri, x 6772
Bonnie Braganza x 7340

PURPOSE/ACTION: Informational

DEADLINE: None

BACKGROUND:

The integrated Pyromed 550 system of Monarch Waste Technologies operating on the Nambe Pueblo is considered a medical waste incinerator. Monarch is required to do initial performance tests (IPT) to meet the New Source Performance Standard (NSPS) for Hospital Medical/Infectious Waste Incinerator (HMIWI) at 40 CFR 60 Subpart Ec. These tests set the site-specific operating parameter limits (OPLs) that will be incorporated into the Title V operating permit for Monarch.

CURRENT STATUS:

On May 20, 2019, Monarch Waste Technologies notified EPA Region 6 that it completed a retest to demonstrate initial compliance with the dioxins/furans (D/F) emission limitation at its hospital/medical/infectious waste incinerator located on the Nambe Pueblo. The retest was carried out under a second modification to the December 4, 2018, Administrative Order on Consent (AOC) that allowed the company to conduct initial performance after it lost the authority to operate. The retest was necessary because preliminary results from the initial performance test indicated the D/F emissions exceeded the compliance limit.

In November 2019, Monarch lost the authority to operate because it did not submit a complete operating permit application within twelve months of commencing operations, since the initial performance tests (IPT) that would determine the operating permit limits was not done. The first modification to the AOC was signed on December 21, 2018 provided Monarch with additional time to perform the IPT, which they completed on February 22, 2019. EPA has provided updates on the status of the operations and the IPT implementation to the Nambe Pueblo government.

Commented [KC1]: This was pulled from the WAR we prepared this week.

Region 6 Air Permits still has not declared the title V operation permit application complete and will only do so until the final testing report has been submitted and results indicate that the source is in compliance with 40 CFR 60 Subpart Ec requirements. Once EPA determines that all requirements are met, then EPA will draft a title V operating permit for the source and begin further consultation work with the Nambe Pueblo and adjacent Tribal nations.

At the same time, at the request of Monarch, EPA Headquarters is evaluating a new design of the system for commercial use at other locations in the United States, a design Monarch believes would ensure the system is not subject to the NSPS for HMIWIs, 40 CFR 60 Subpart Ec.

ENVIRONMENTAL/COMMUNITY/GOVERNMENTAL CONCERNS:

NMED expressed interest and concerns as early as August 2016 about the facility. Adjacent Tribal nations have raised questions to EPA Region 6 about potential air emissions/pollutants and the permitting process. EPA Air Permits and Air Enforcement have worked with the Region 6 Tribal Office to give periodic updates to the Tribal nations.

EPA does not have any regulatory requirements with respect to the storage and transportation of the medical waste, which is of interest to the Nambe Pueblo government and NMED.

There are residential dwellings roughly 800-1000 feet from the facility.

TECHNICAL and REGULATORY REQUIREMENTS:

The company has represented that their projected emissions are below the minor NSR permitting thresholds for criteria pollutants on Tribal lands. The company has not indicated that there are any hazardous air pollutant (HAP) emissions from the unit. The company has modified their unit to fire low sulfur diesel for initial startup and operational stability of continuous overall system operations in winter months. It is unclear that this was factored into their original emission calculations to determine minor NSR permitting applicability, but they did use diesel during the initial performance test.

40 CFR 60 – Subpart Ec requires the incinerator to have a complete Title V operating permit application within one year of starting its operation. A complete permit application must include the site-specific OPLs included. As noted earlier, EPA Region 6 Air Permits declared the title V permit application from Monarch as incomplete in October 2018 and therefore the company could not conduct normal operations of the incinerator. The AOC allowed Monarch to operate for the IPT and determination of OPLs. Upon determination that the recent performance testing and the OPLs comply with Subpart Ec., Monarch will provide a complete permit application to EPA and seek EPA clarification that they can operate while waiting on permit issuance.

EPA air regulations requiring an air permit do not have requirements for regulating transport and storage specifically, but they do require the company to have a waste management plan. We've advised the Nambe Pueblo of this issue due to questions about their ability to regulate or require onsite waste storage conditions at the facility.

RECOMMENDATIONS:

None at this time.

Braganza, Bonnie

From: Kuehn, Elizabeth, NMENV <Elizabeth.Kuehn@state.nm.us>
Sent: Thursday, August 04, 2016 3:10 PM
To: Braganza, Bonnie
Cc: LeDoux, Erica
Subject: RE: Synergy Pyrolysis Permit Application

Bonnie,

We are available next Thursday at 2:00 pm MDT. Please let me know if this time works and I'll send out a calendar invite.

Liz

Elizabeth Bisbey-Kuehn
Minor Source Manager
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, NM 87505-1816
Phone: (505)476-4338 Fax:(505)476-4375
<http://www.nmenv.state.nm.us/aqb>

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This email is intended to serve as general guidance and is in no way a formal statement of Department policy. Unique operating conditions may result in different determinations and may require a site specific analysis to accurately determine requirements and applicability.

From: Braganza, Bonnie [mailto:Braganza.Bonnie@epa.gov]
Sent: Wednesday, August 03, 2016 1:43 PM
To: Kuehn, Elizabeth, NMENV <Elizabeth.Kuehn@state.nm.us>
Cc: LeDoux, Erica <LeDoux.Erica@epa.gov>
Subject: RE: Synergy Pyrolysis Permit Application

I have been contacted by David Cardenas and I am waiting to get the actual emission data and operations. I have given him the website for filing an application etc. Do you have information that you will share with me. At this time I only have information he has provided us and we feel that they are exempted from the 40 CFR 62.14400 (b)(5) . I am available next week all days except Tuesday.

If I do get additional information, I can share at our call next week. Thank you for sharing with us

Bonnie Braganza P.E.
Air Permits
US Environmental Protection Agency
Region 6
1445 Ross Ave, Dallas TX 75202
214-665-7340

The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

From: Kuehn, Elizabeth, NMENV [mailto:Elizabeth.Kuehn@state.nm.us]
Sent: Wednesday, August 03, 2016 2:34 PM
To: Braganza, Bonnie <Braganza.Bonnie@epa.gov>

Cc: Sanchez, Rosanne, NMENV <rosanne.sanchez@state.nm.us>

Subject: Synergy Pyrolysis Permit Application

Hi Bonnie,

Would you or someone from your office be available for a conference call with NMED to discuss emission factors and emission calculations for Synergy's medical waste pyrolysis units? NMED Air Quality Bureau staff have held several meetings with the company and I understand the first installation of this technology will be on Indian Land and, thus, under your regulatory jurisdiction.

Please let me know your availability for a conference call sometime during the next week. We look forward to speaking with you.

Regards,
Liz

Elizabeth Bisbey-Kuehn
Minor Source Manager
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, NM 87505-1816
Phone: (505)476-4338 Fax:(505)476-4375
<http://www.nmenv.state.nm.us/aqb>

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This email is intended to serve as general guidance and is in no way a formal statement of Department policy. Unique operating conditions may result in different determinations and may require a site specific analysis to accurately determine requirements and applicability.

Braganza, Bonnie

Subject: Synergy Medwaste - applicability
Location: Conference call

Start: Mon 9/12/2016 2:00 PM
End: Mon 9/12/2016 3:00 PM

Recurrence: (none)

Meeting Status: Meeting organizer

Organizer: Braganza, Bonnie

Required Attendees: Braganza, Bonnie; Mia, Marcia; Hambrick, Amy; Nizich, Greg; David Cardenas; Kaleri, Cynthia;
srydeen@nambepueblo.org

Optional Attendees: LeDoux, Erica; steven@nambetribes.com; Philip Tenorio; Kuehn, Elizabeth, NMENV; Poley, Richard, NMENV; Schooley, Ted, NMENV; Steven Tenorio; Sanchez, Rosanne, NMENV

Discussion on Synergy Medwaste pyrolysis

1-866-299-3188 Code 214 665-7340

Synergy Medwaste has stated that the medical waste will be coming from several states and this will be a commercial operation.

EPA needs to obtain sufficient information to make a decision for the exemption in NSPS Ec. 40 CFR 60.51(c)



Attached is the non-CBI version of the process.

I have also invited Steve from the Pueblo of Nambe since he requested to be on the call.

Thank you for making time to participate in this discussion

Bonnie Braganza P.E.
Air Permits
US Environmental Protection Agency
Region 6
1445 Ross Ave, Dallas TX 75202
214-665-7340

The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

Braganza, Bonnie

From: David Cardenas <dcardenas@synergyrenew.com>
Sent: Friday, August 12, 2016 12:56 PM
To: Braganza, Bonnie
Subject: RE: Ohkay Owingh New Mexico
Attachments: removed.txt

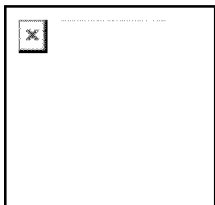
Thanks Bonnie! I will get with our consultants to get something set up by Wednesday or Thursday of next week. In the meantime, we might be changing our site location to the Nambe pueblo since they have an existing building that is better fit for our timeline delivery. I will know more details by the time we talk next to keep you in the loop as we go.

All the best,

Synergy Medwaste, LLC

David Cardenas | CEO

972.392.6180 Main | 214.442.1559 Direct | 972.768.6885 Cell
16400 North Dallas Parkway, Suite 400 | Dallas | TX 75248



www.synergymedwaste.com

From: Braganza, Bonnie [mailto:Braganza.Bonnie@epa.gov]
Sent: Wednesday, August 10, 2016 2:35 PM
To: David Cardenas
Subject: RE: Ohkay Owingh New Mexico

Monday and Tuesdays, I will not be in the office. Thursday or Wednesday afternoon may be better. However I will need something to review like the project, emissions and process etc. prior to the call.

Bonnie Braganza P.E.
Air Permits
US Environmental Protection Agency
Region 6
1445 Ross Ave, Dallas TX 75202
214-665-7340

The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

From: David Cardenas [mailto:dcardenas@synergyrenew.com]
Sent: Wednesday, August 10, 2016 2:13 PM
To: Braganza, Bonnie <Braganza.Bonnie@epa.gov>
Subject: RE: Ohkay Owingh New Mexico

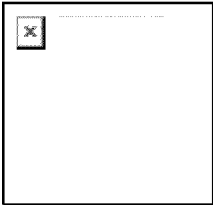
Bonnie, I hope your week is going well! Our emissions/environmental consultants indicated that they will be completing the threshold "comparison" chart sometime in the next few days. Once he has that complete and you have reviewed things, could it be possible to set up a conference call on Monday or Tuesday with our consultants and yourself to talk through specifics?

Synergy Medwaste, LLC

David Cardenas | CEO

972.392.6180 Main | 214.442.1559 Direct | 972.768.6885 Cell

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www.synergymedwaste.com

From: Braganza, Bonnie [<mailto:Braganza.Bonnie@epa.gov>]

Sent: Tuesday, August 02, 2016 3:46 PM

To: David Cardenas

Subject: RE: Ohkay Owingh New Mexico

This will come under the minor NSR permitting rule at: <https://www.epa.gov/caa-permitting/tribal-nsr-implementation-epas-south-central-region>

I may have sent you an extracted table from the rule but if any emissions are greater than the thresholds in the attachment, a minor NSR permit will be needed.

I also want you to know that when EPA is the permitting authority a screening analysis for ESA and NHPA must be done and in Region 6. The procedure is attached. We do have our tribal consultation procedures where we inform all tribes that have an interest (surrounding tribes and States as well) or may have had an interest in that area.

Regarding these analysis it is very important that you indicate if there will be any ground disturbance with the project and if not, provide EPA the documents from BIA or another Federal agency that would have addressed the ESA and NHPA concerns.

I realize that this is a good project, but we may need to have community outreach because of the public's perception of medical waste incinerator in their neighborhood.

First let's get the information together. All the forms and requirements are on the above website and I will be happy to discuss with you the needs in the form. I am not sure what you mean by 25 tpy threshold, because on tribal land it is based on the emissions for each pollutant with VOC > 5 tpy and is lower for PM that will require a mNSR permit. The mNSR thresholds document is attached.

Bonnie Braganza P.E.

Air Permits

US Environmental Protection Agency

Region 6

1445 Ross Ave, Dallas TX 75202

214-665-7340

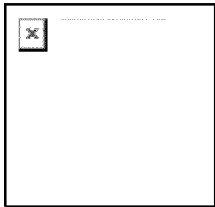
The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

From: David Cardenas [<mailto:dcardenas@synergyrenew.com>]
Sent: Tuesday, August 02, 2016 12:17 PM
To: Braganza, Bonnie <Braganza.Bonnie@epa.gov>
Cc: 'Ed Cardenas' <pdsbuilding@comcast.net>
Subject: RE: Ohkay Owingh New Mexico

Bonnie, I thought I would check back in with you following our discussions last week. I recall you were meeting with others in your office to discuss another Pyrolysis system (in Louisiana I think) and some issues they had that are causing questions on our system and application with medical waste destruction. Is there any information you need to clear up the fact that our system is indeed true Pyrolysis and identify the comparative differences that are unique to our system to avoid being put in the same class with whatever system that you all had issues with?

As it relates to the NSR permit application you sent us, our environmental consultant indicated they will have a comparison chart completed this week. The good news is he indicated that we will have combined total emissions that are far below the 25 ton yearly total! Considering the permit is applicable for emissions >25tons/yr or <100tons/yr, is there another permit application that you can give us or that is required that applies to ours since we are far below the 25ton threshold?

Synergy Medwaste, LLC
David Cardenas | CEO
972.392.6180 Main | 972.392.6189 Direct | 972.768.6885 Cell
16400 North Dallas Parkway, Suite 400 | Dallas | TX 75248



www.synergymedwaste.com

From: Braganza, Bonnie [<mailto:Braganza.Bonnie@epa.gov>]
Sent: Tuesday, July 12, 2016 3:26 PM
To: David Cardenas
Subject: RE: Ohkay Owingh New Mexico

Please check 40 CFR 62.14400 (b)(5) to determine if your facility qualifies for an exemption from the rule. If so then a title V permit is not required because of the exemption in 5 " Own or operate a pyrolysis unit (defined in 40 CFR 62.14490) processing hospital waste and/or medical/infectious waste. "

What are your estimated emissions from this facilities? Attached are the minor NSR thresholds for which a site specific permit is required. Also please review the needed information for the minor NSR permit application at: https://www.epa.gov/sites/production/files/2015-09/documents/new_source_general_application_form121713r6.pdf

I will be in the office and available on Thursday or Friday of this week if you would like to talk. Let me know times of your availability and then we can have a conference call. Also be aware that the ESA and NHPA information is also needed and that may not be difficult if your facility is in an already constructed building.

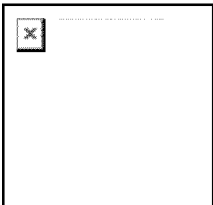
Bonnie Braganza P.E.
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US Environmental Protection Agency
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1445 Ross Ave, Dallas TX 75202
214-665-7340

The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

From: David Cardenas [<mailto:dcardenas@synergyrenew.com>]
Sent: Tuesday, July 12, 2016 12:03 PM
To: Braganza, Bonnie <Braganza.Bonnie@epa.gov>
Subject: RE: Ohkay Owingh New Mexico

Thanks for the quick response and I look forward to hearing your feedback. As a side note, our permitting consultant "Ensafe" presented the technology to the TCEQ on a site we have in the pipeline to do in Houston. They indicated that a title V permit would not be needed here for our Texas site since we are far below the emission profile requirements, was this incorrect?

Synergy Medwaste, LLC
David Cardenas | CEO
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From: Braganza, Bonnie [<mailto:Braganza.Bonnie@epa.gov>]
Sent: Tuesday, July 12, 2016 11:57 AM
To: David Cardenas
Subject: RE: Ohkay Owingh New Mexico

Thank you for this information. I will review it and get back to you by the end of this week. When do you plan construction?

The EPA rule regarding medical waste incinerators is at :
<https://www.gpo.gov/fdsys/pkg/FR-2013-05-13/pdf/2013-09427.pdf>

You will need a title V permit as well.

Bonnie Braganza P.E.
Air Permits
US Environmental Protection Agency
Region 6
1445 Ross Ave, Dallas TX 75202
214-665-7340

The world moves at such a rapid rate that waiting to implement changes will leave you two steps behind

From: David Cardenas [<mailto:dcardenas@synergyrenew.com>]
Sent: Tuesday, July 12, 2016 11:25 AM
To: Braganza, Bonnie <Braganza.Bonnie@epa.gov>
Cc: naomi.archuleta@ohkay.org; 'Ed Cardenas' <edcardenas@synergymedwaste.com>; 'Ron Lovato' <r.lovato@tsaycorp.net>
Subject: Ohkay Owingh New Mexico

Bonnie, I left you a voice this morning and thought I would follow up with this email. We are in pre-development efforts to co-develop a small scale Medical Waste destruction facility with our teaming partner Tsay Corporation on a piece of property located within the Ohkay Owingeh tribal jurisdiction in New Mexico. Naomi Archuleta wanted us to contact you to outline our approach and ask for your guidance to secure proper authorizations to allow us to move forward. Allow me to outline a few facts to help you get an overview on our approach;

1. This facility is NOT an incinerator but rather continuous Pyrolysis system with a mindset to develop a clean and affordable small scale solution to help hospitals avoid the increasing cost of long distance transportation for waste items that are typically incinerated.
2. Our system is NOT a prototype but rather a proven system with over 17 years of operational history in the UK with the most recent facility located in Scotland permitted under EU standards. Here is a video link to our system. <https://www.dropbox.com/s/halzt7pv2q23kl6/PyroMed%20550%20Promo-Video.mp4?dl=0>
3. Our facility/system emissions profile is a borderline Technical service unit category but would most likely conform to the lower end of the Minor Source category for this use.
4. Our Oxidizer complies to EU standards (2 seconds res time) in comparison to US standards (0.5 seconds) insuring total combustion of all gases in a separate chamber.
5. The system destroys a maximum of 550 lbs/hr of waste.
6. The types of Medwaste we will be processing are categorized as typical Regulated Medical Waste (RMW-red containers) and other items that are required to be incinerated (RCRA and Non RCRA -pharmaceuticals, pathological, chemo –Black, Yellow and Blue containers).

Anyways, I would love the opportunity to discuss this project with you at your next available time and look forward to your thoughts and direction as we move forward to deliver this proven non-incineration solution.

All the best,

Synergy Medwaste, LLC
David Cardenas | CEO
972.392.6180 Main | 972.768.6885 Direct
16400 North Dallas Parkway, Suite 400 | Dallas | TX 75248



www.synergymedwaste.com

To: Lannen, Justin[Lannen.Justin@epa.gov]
From: Larson, Darrin[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AF2D4B28B0B842B2BAF3DF180786B67E-LARSON, DARRIN]
Sent: Tue 5/7/2019 3:13:07 PM (UTC)
Subject: FW: Information for Monarch Waste Technologies Discussion
[Attachment'D' Precedent Pyrolysis exempt.pdf](#)
[DOE Report SandiaPyrolysisAnalysis.pdf](#)
[EPA Coaltec Response.pdf](#)
[EPA recap of correspondence.pdf](#)
[MWT Pyrolysis exemption request 12-10-18.pdf](#)
[MWT Update_05_02_19.docx](#)
[Attachment "B" Precedent.pdf](#)
[Attachment 'A' Process Diagram & Narritive.pdf](#)
[Attachment 'C' Pyromed vessels.pdf](#)

Darrin Larson
Chief, Air Permitting Enforcement Section (ECDAP)
U.S. EPA Region 6
Office: 214-665-7115
Mobile: 972-467-5509

From: Mia, Marcia
Sent: Monday, May 06, 2019 7:42 AM
To: Larson, Darrin <Larson.Darrin@epa.gov>; Thompson, Steve <thompson.steve@epa.gov>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: FW: Information for Monarch Waste Technologies Discussion

FYI, we send this up for the Monarch briefing with Patrick.

I added Coaltec, as an example of the type of guidance we provide when there isn't a site specific application, as is the case of Monarch. In other words, Mr. Cardenas is getting what everyone else receives in these theoretical situations.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

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From: Scinta, Robert
Sent: Friday, May 03, 2019 9:14 AM
To: Traylor, Patrick <traylor.patrick@epa.gov>
Cc: Segall, Martha <Segall.Martha@epa.gov>; Duffy, Rick <Duffy.Rick@epa.gov>; Carbone, Chad <Carbone.Chad@epa.gov>; Mia, Marcia <Mia.Marcia@epa.gov>; Hindin, David <Hindin.David@epa.gov>; Dombrowski, John <Dombrowski.John@epa.gov>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>; Thompson, Steve <thompson.steve@epa.gov>; Larson, Darrin <Larson.Darrin@epa.gov>
Subject: Information for Monarch Waste Technologies Discussion

Hello Mr. Traylor,

Please see the attached documents in preparation for the discussion on Monarch Waste Technologies, scheduled for this Tuesday, May 7th. Marcia was able to update the attached Word document (MWT_Update_05_02_19.docx) to provide an overview and current status of the issue. The remaining eight .pdf files are included as additional information.

Thank you.

ED_006024A_00003515-00001

Bob Scinta, Chief
Air Branch
Monitoring, Assistance, and Media Programs Division
Office of Compliance/OECA
U.S. EPA
ph: (202) 564-7171
cell: (202) 573-6442

From: Traylor, Patrick
Sent: Thursday, May 02, 2019 1:10 PM
To: Mia, Marcia <Mia.Marcia@epa.gov>
Subject: RE: exemption update?

Let's get together with as small a number of knowledgeable people as possible so I can come up to speed on what he's requesting, what the facts (as we understand them) show, and what we'd be able to say to him. Once I've been briefed, we can decide together how to engage David.

Patrick Traylor
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
202.809.8796 (m)
202.564.5238 (o)

From: Mia, Marcia
Sent: Thursday, May 2, 2019 1:08 PM
To: Traylor, Patrick <traylor.patrick@epa.gov>
Subject: RE: exemption update?

Sorry, one more point. The Monarch system isn't just a pyrolysis tube. It also has a char vessel. The char vessel is problematic for the pyrolysis exemption, because it is definitely exothermic. But it may not support combustion, so it still may not be a HMIWI, depending on what they do with the syngas which is generated (is it combusted). The draft letter attempts to sort out those possible outcomes, but not a yes or no answer. I think he should be happy with the letter, unless he is looking for an EPA seal of approval to put on his marketing materials.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

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From: Mia, Marcia
Sent: Thursday, May 02, 2019 12:50 PM
To: Traylor, Patrick <traylor.patrick@epa.gov>
Subject: RE: exemption update?

Hi Patrick,

I am sorry he is frustrated with us, but we have done our best over the past four years to help Mr. Cardenas. R6 has gone above and beyond to help him with testing and permitting his unit in NM, which *is* subject the rule. The unit currently is shut down and only allowed to operate under an AOC to complete their performance testing, as they are about 1.5 years past their compliance date at this point, and the most recent report yet again was deficient.

In his current request, he wants a yes or no answer to a hypothetical unit, with at least three different hypothetical applications. There is no way to get to yes for him, without a set of facts. I would prefer not to say “no” because I believe that in the right “specific” scenario, the unit could be used without triggering the hospital/medical/infectious waste incinerator (HMIWI) rules. But that unit doesn’t yet exist.

To his point that testing was conducted that provided “evidence showing proof it is Pyrolysis” – the definition of pyrolysis in the HMIWI rule is that the process is endothermic. According to the test report:

[It] is difficult to verify to the standard of endothermicity because the system is not adiabatic nor batch, which might enable an energy balance assessment. Instead, SNL describes that their results are used to help characterize the effluent chemicals as indicators of a pyrolysis process.

Unfortunately, the exemption is not based on the characterization of “effluent chemicals as indicators of a pyrolysis process.”

Furthermore, the definition of a HMIWI at §60.51c is “any device that combusts any amount of hospital waste and/or medical/infectious waste.” To the point of combustion, the report says:

“[t]here remains some uncertainty that there could be partial combustion in the chamber, but the magnitude of the pyrolysis products found suggest that if combustion occurs it is minor. The report also suggests that the “next sensible step might be to test the effluent emissions and characterize those in comparison to incineration products” and that “[c]ertifying complete lack of combustion may require additional work, which could include a flame detector (perhaps an OH* or CH* detector.)”

On these two points alone, we could give him a “no” answer, but again, I was trying instead to provide helpful guidance to him regarding how he might get to “yes.”

Would you like for me to get some time your calendar to discuss in more detail, or set up a call with Mr. Cardenas? We should include R6, as well, in that call.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

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From: Traylor, Patrick
Sent: Thursday, May 02, 2019 11:52 AM
To: Mia, Marcia <Mia.Marcia@epa.gov>
Subject: FW: exemption update?

Marcia:

I’m not close enough to this matter to be able to engage productively with David. He is looking for a yes/no answer (with an explanation) to a request for an exemption.

Patrick

Patrick Traylor
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
202.809.8796 (m)
202.564.5238 (o)

From: David Cardenas <davidc@monarchwastetechologies.com>

Sent: Thursday, May 2, 2019 11:47 AM

To: Traylor, Patrick <traylor.patrick@epa.gov>

Subject: RE: exemption update?

Thank you Patrick.

While I appreciate Marcia's efforts to get us a letter that would help us understand our obligations for future facilities (which is something we already understand), I looked back on everything for the past 3 years and couldn't find anything other than discussions and requests regarding expectations for receiving an Exemption for our unit as allowed and defined under regulation.

So, to clarify your point, an Exemption is what we are requesting.

Between you and I Patrick, man I feel like I'm in the twilight zone... shocked to think I am back to the start again wondering if someone wants me to give up, which is not an option for me.

I just do not understand why it's so hard for the EPA to determine if our unit, as defined under the rule (short definition with three sentences), complies to be exempt as a Pyrolysis unit. It either is or isn't. Given the fact that we have a solid report from combustion / Pyrolysis experts at the Department of Energy with laboratory data evidence showing proof it is Pyrolysis should validate this point alone, coupled with all the other data we have given the EPA since 2016. Yet despite all of this, the EPA (or someone inside) is refusing to acknowledge these facts (for some reason) and is not allowing us to have rights under this exemption which other companies have been granted in the past. My question is why?

I want to be extremely respectful of your time and want to avoid frustrating you any more than I already have as I know your helping us communicate this fundamental yet simple point. However, since my efforts have obviously fallen short of communicating our goal to secure an Exemption as we have requested since day one, what do you suggest we do at this point?

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

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From: Traylor, Patrick <traylor.patrick@epa.gov>

Sent: Thursday, May 2, 2019 7:58 AM

To: David Cardenas <davidc@monarchwastetechologies.com>

Subject: RE: exemption update?

David:

I've been in touch with Marcia on this and I've asked her to put together a timeline by which we can get you an answer.

She asked me to clarify with you that the EPA is not working on an exemption letter, but is instead working on—for lack of a better term—a regulatory compliance assistance letter that should help the company understand its obligations more clearly for future facilities. I gather from some of the exchange of correspondence that the company understands that, but I wanted to be clear.

Warm regards,
Patrick

ED_006024A_00003515-00004

Patrick Traylor
Deputy Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
202.809.8796 (m)
202.564.5238 (o)

From: David Cardenas <davidc@monarchwastetechologies.com>

Sent: Tuesday, April 30, 2019 2:03 PM

To: Traylor, Patrick <traylor.patrick@epa.gov>

Subject: FW: exemption update?

Greetings Patrick! I hope you are doing great. Well, I have been pressing on this exemption request since December and being the "squeaky wheel" as much as possible. After running all of the hurdles with region 6 and their interaction with headquarters in WA, it appears now that they will be reaching out to you for direction (see below) to get us a letter of approval (finally). Please let me know if you need me to provide anything else to you so we can turn the page on this 4 year quest and finally move forward.

All the best,

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

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From: Mia, Marcia <Mia.Marcia@epa.gov>

Sent: Tuesday, April 30, 2019 10:48 AM

To: David Cardenas <davidc@monarchwastetechologies.com>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>

Subject: RE: exemption update?

Hi David,
We will discuss options with our management and get back to you.

Since your letter came in at Deputy Assistant Administrator level, we may need to go back to that level for direction – which could take some time to get on calendars.

We will keep you posted.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

From: David Cardenas <davidc@monarchwastetechologies.com>
Sent: Tuesday, April 30, 2019 11:15 AM
To: Mia, Marcia <Mia.Marcia@epa.gov>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: RE: exemption update?

Marcia, that makes perfect sense and thank you so much for taking the time to provide that crystal clear explanation. First off, I know you and Cynthia have spent way more time on our request than most (I'm sorry) and I thank you for hanging with us. I also know that this request applies to the next systems (we are in process of developing) and does not apply to our Nambe Facility. With that said, is there any way possible that you can give us some type of response that would be meaningful enough (complies to the Pyrolysis exemption) with a "subject to" the review of NSHM on certain waste items? This will allow us to move forward on other efforts and put this subject on pause while the NSHM folks can regroup and chime in. Is this possible please?

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

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From: Mia, Marcia <Mia.Marcia@epa.gov>
Sent: Tuesday, April 30, 2019 9:31 AM
To: David Cardenas <davidc@monarchwastetechologies.com>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: RE: exemption update?

Hi David,
Sorry to confuse you with yet more EPA jargon. Non-hazardous secondary material (NHSM) is the umbrella term for materials which are solid wastes (of which medical waste is an example) when combusted. There are "outs" from NSHM when the solid waste is used as a fuel or ingredient. In order to provide you with a more complete response to your letter, we wanted to explain how NHSM would apply if the syngas is burned in a boiler, engine or flare. So, in this way you might say it is an "added benefit" to your request.

Since NSHM is "owned" by our RCRA folks, we needed to include them in the consultation and drafting of the response.

Marcia B Mia
Air Branch
Office of Compliance
2227A WJCS
U.S. Environmental Protection Agency
202-564-7042

From: David Cardenas <davidc@monarchwastetechologies.com>
Sent: Monday, April 29, 2019 7:10 PM

ED_006024A_00003515-00006

To: Mia, Marcia <Mia.Marcia@epa.gov>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>

Subject: RE: exemption update?

Marcia, I am so sorry to hear about that and my prayers are with him for sure.

Apologies if I missed something here but can you help me understand if this “non-hazardous secondary material part” is in addition to the waste that has already been defined as medical waste outlined in our exemption request? Or is this another type of waste that you all feel needs to be included as an added benefit to our request? I’m a bit confused and need your help to understand your path forward for us.

All the best,

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

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From: Mia, Marcia <Mia.Marcia@epa.gov>

Sent: Monday, April 29, 2019 3:22 PM

To: David Cardenas <davidc@monarchwastetechnologies.com>; Kaleri, Cynthia <kaleri.cynthia@epa.gov>

Subject: RE: exemption update?

Hi David,

I haven’t even had a chance to let Cindy know, but the RCRA contact who holds the expertise on the non-hazardous secondary material part went into the hospital last week for emergency heart surgery. He will be out for 4-6 weeks. They have not yet determined if they will be able to assign someone else (or if there is someone else with the expertise needed).

We will keep you posted.

Marcia B Mia

Air Branch

Office of Compliance

2227A WJCS

U.S. Environmental Protection Agency

202-564-7042

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From: David Cardenas <davidc@monarchwastetechnologies.com>

Sent: Monday, April 29, 2019 4:16 PM

To: Kaleri, Cynthia <kaleri.cynthia@epa.gov>

Cc: Mia, Marcia <Mia.Marcia@epa.gov>

Subject: RE: exemption update?

Hi Cynthia / Mia, I hope your weekend was relaxing. I wanted to check in with you to see if we can get some kind of idea on

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timing to the exemption request finalized. Do we need a call to go over your final questions or do you have all you need?

Monarch Waste Technologies

David Cardenas | Principal / Co-Founder

Dallas Office 972.768.6885

12801 North Central Expressway Suite 1600 | Dallas | TX 75243

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From: Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Sent: Wednesday, April 10, 2019 4:22 PM
To: David Cardenas <davidc@monarchwastetechnologies.com>
Cc: Mia, Marcia <Mia.Marcia@epa.gov>
Subject: RE: exemption update?

Hello David,

We had a call earlier this week with our RCRA group (helping with the path forward) and are on course for drafting an agency response given the nature of the request (other units yet to be constructed, not the Nambe unit). I am preparing for a week long field effort and am going to be out of the office over the next week to implement that effort, but you may want to let me know when you are planning on traveling to DC, or feel free to call Marcia directly during the interim to let her know of your timeframe for traveling to DC.

Thanks,

Cynthia J. Kaleri
ADAM-CAP Coordinator/CAA Enforcement Officer
EPA Region 6

Phone (214) 665-6772

Mailing Address

Attention: Cynthia J. Kaleri (6EN-AA)
United States Environmental Protection Agency
1445 Ross Avenue
Dallas, TX 75202-2733

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From: David Cardenas <davidc@monarchwastetechnologies.com>
Sent: Wednesday, April 10, 2019 1:53 PM
To: Kaleri, Cynthia <kaleri.cynthia@epa.gov>
Subject: exemption update?

Hi Cynthia! Separate from our facility discussions (weekly hours report coming at you tomorrow)....

Any word from Marcia Mia on our letter? I know you must have more important / pressing things to do than translate messages

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between her and I so if its easier, I can contact her (like before) and save you the time? let me know either way please as I have another meeting scheduled in WA coming up and was hoping we could get this done by then.

All the best,

Monarch Waste Technologies

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